Registration No. 333-

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM S-1
REGISTRATION STATEMENT

Under
The Securities Act of 1933

VENTYX BIOSCIENCES, INC.

(Exact name of Registrant as specified in its charter)

Delaware	**2834**	**83-2996852**
(State or other jurisdiction of incorporation or organization)	**(Primary Standard Industrial Classification Code Number)**	**(I.R.S. Employer Identification Number)**

662 Encinitas Blvd, Suite 250
Encinitas, California 92024
(760) 593-4832

(Address, including zip code, and telephone number, including area code, of Registrant's principal executive offices)

Raju Mohan, PhD
Chief Executive Officer
Ventyx Biosciences, Inc.
662 Encinitas Blvd, Suite 250
Encinitas, California 92024
(760) 593-4832

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Martin J. Waters **Jason Skolnik** **Robert L. Wernli, Jr.** **Wilson Sonsini Goodrich & Rosati** **Professional Corporation** **12235 El Camino Real** **San Diego, California 92130** **(858) 350-2300**	**Christopher Krueger** **Chief Business Officer** **Ventyx Biosciences, Inc.** **662 Encinitas Blvd, Suite 250** **Encinitas, California 92024** **(760) 593-4832**	**Charles S. Kim** **Kristin VanderPas** **Dave Peinsipp** **Denny Won** **Cooley LLP** **4401 Eastgate Mall** **San Diego, California 92121** **(858) 550-6000**

Approximate date of commencement of proposed sale to the public: As soon as practicable after this registration statement becomes effective.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. ☐

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐ Accelerated filer ☐ Non-accelerated filer ☒ Smaller reporting company ☒ Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act. ☐

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	**Proposed Maximum Aggregate Offering Price(1)(2)**	**Amount of Registration Fee**
Common Stock, $0.0001 par value per share	$	$

(1) Estimated solely for the purpose of calculating the registration fee in accordance with Rule 457(o) of the Securities Act of 1933, as amended.
(2) Includes the aggregate offering price of additional shares that the underwriters have the option to purchase.

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the registration statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

The information contained in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and is not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED , 2021

PRELIMINARY PROSPECTUS

Shares

Common Stock

We are offering shares of our common stock. This is our initial public offering, and no public market currently exists for our common stock. We expect the initial public offering price to be between $ and $ per share. We intend to apply to list our common stock on the Nasdaq Global Market under the symbol "VTYX."

We are an "emerging growth company" and a "smaller reporting company" as those terms are defined under the federal securities laws and, as such, we have elected to comply with certain reduced reporting requirements for this prospectus and may elect to do so in future filings.

Investing in our common stock involves a high degree of risk. Please read "Risk Factors" beginning on page 11 of this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

	PER SHARE	TOTAL
Initial Public Offering Price	$	$
Underwriting Discounts and Commissions (1)	$	$
Proceeds to Ventyx Biosciences, Inc., before expenses	$	$

(1) See "Underwriting" beginning on page 170 for additional information regarding underwriter compensation.

Delivery of the shares of common stock is expected to be made on or about , 2021.

We have granted the underwriters an option for a period of 30 days to purchase an additional shares of our common stock. If the underwriters exercise the option in full, the total underwriting discounts and commissions payable by us will be $ and the total proceeds to us, before expenses, will be $.

Jefferies **Evercore ISI** **Piper Sandler**

LifeSci Capital

Prospectus dated , 2021

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Through and including , 2021 (the 25th day after the date of this prospectus), all dealers effecting transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.

Neither we nor any of the underwriters have authorized anyone to provide any information or to make any representations other than those contained in this prospectus or in any free writing prospectuses we have prepared. Neither we nor any of the underwriters take responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus is an offer to sell only the shares offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus is current only as of its date, regardless of the time of delivery of this prospectus or of any sale of common stock.

For investors outside of the United States: Neither we nor any of the underwriters have done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of our common stock and the distribution of this prospectus outside the United States.

PROSPECTUS SUMMARY

This summary highlights selected information contained elsewhere in this prospectus and is qualified in its entirety by the more detailed information and financial statements included elsewhere in this prospectus. It does not contain all of the information that may be important to you and your investment decision. You should carefully read this entire prospectus, including the sections titled "Risk Factors," "Special Note Regarding Forward-Looking Statements," "Management's Discussion and Analysis of Financial Condition and Results of Operations," and our consolidated financial statements and related notes. In this prospectus, unless the context requires otherwise, references to "we," "us," "our," "Ventyx" or "the Company" refer to Ventyx Biosciences, Inc. and its subsidiaries taken as a whole.

Overview

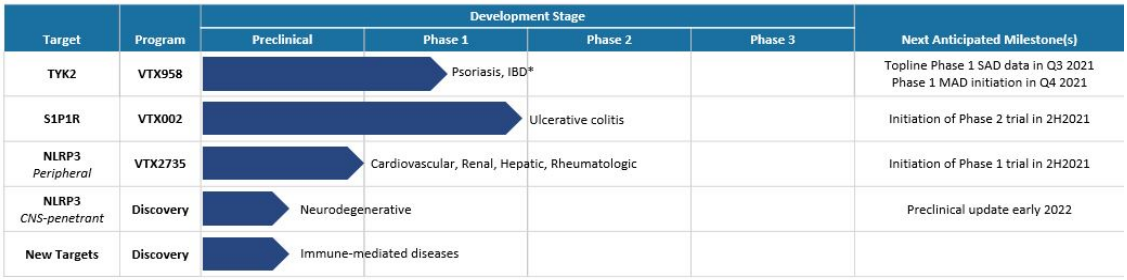
We are a clinical-stage biopharmaceutical company focused on advancing new therapies for millions of patients living with inflammatory diseases and autoimmune disorders. We believe our ability to internally discover and develop differentiated product candidates with potential to be best-in-class and first-in-class in an efficient manner, allows us to address well-established, yet unsatisfied, multi-billion-dollar commercial markets and positions us to become a leader in the immunology market.

Our lead product candidate is VTX958, a potent, oral and highly selective clinical-stage tyrosine kinase type 2 (TYK2) inhibitor, which, we believe, has best-in-class potential. Its high selectivity for TYK2 without detectable inhibition of other Janus kinase (JAK) isoforms in preclinical studies supports the potential to avoid toxicities associated with broader JAK inhibition and, thus, other JAK inhibitors. We believe VTX958 has the potential to address a broad range of immune-mediated diseases, such as psoriasis, inflammatory bowel disease (IBD), psoriatic arthritis and lupus, each of which represent multi-billion-dollar market opportunities. We plan to develop VTX958 initially for psoriasis and IBD, among other potential indications.

In addition, we are developing VTX002, a potent, oral and highly selective Phase 2-ready sphingosine 1 phosphate receptor 1 (S1P1R) modulator for ulcerative colitis (UC). S1P1R is a clinically validated target and in our Phase 1 trial VTX002 was well tolerated at all doses tested and showed a robust, dose-dependent, and steady-state reduction in absolute lymphocyte count (ALC) of up to 65%. Based on these data, we plan to initiate a Phase 2 randomized, placebo-controlled clinical trial in the second half of 2021 to pursue the commercial opportunity in UC, which represented approximately $7 billion in worldwide sales in 2020.

We also are developing a comprehensive portfolio of differentiated NOD-like receptor protein 3 (NLRP3) inhibitors to address multiple indications driven by NLRP3 inflammasome activation. Our potent, oral, highly selective and peripherally restricted (does not cross the blood-brain barrier) NLRP3 inhibitor, VTX2735, has been designed to treat systemic inflammatory diseases, such as cardiovascular, hepatic, renal and rheumatologic diseases. In addition to VTX2735, our preclinical NLRP3 inhibitor programs include central nervous system (CNS)-penetrant compounds. Any one of these inflammatory diseases represents a multi-billion-dollar commercial opportunity. VTX2735, our lead NLRP3 candidate, is expected to enter the clinic in the second half of 2021.

The chart below summarizes our current pipeline of preclinical and clinical programs.



*Following the completion of our MAD Phase 1 trial, we intend to initiate Phase 2 trials in psoriasis, IBD and potentially other indications.

VTX958 (TYK2 Inhibitor)

VTX958 is a potent, oral and highly selective inhibitor of TYK2, an intracellular signaling kinase in the JAK family. The JAK signal transduction and activator of transcription (STAT) signaling pathway is implicated in the pathogenesis of numerous inflammatory and autoimmune diseases. By inhibiting TYK2-mediated signal transduction, VTX958 has the potential to suppress chronic inflammation while avoiding inhibition of other related members of the JAK family, such as JAK1, JAK2 and JAK3, thereby reducing the associated risk of infections and other side effects. This high level of selectivity, which is based on results observed in preclinical studies, underpins a safety profile observed in preclinical studies that is differentiated from first-generation JAK inhibitors. In preclinical safety assessments in multiple species, VTX958 has demonstrated a wide safety margin, offering the possibility of exploring higher doses in human proof-of-concept (POC) studies. We believe that this could extend the clinical viability of VTX958 beyond psoriasis to IBD, lupus and other potential indications. We commenced a Phase 1 single-ascending dose (SAD) trial of VTX958 in healthy volunteers in March 2021. Following its completion, we plan to initiate the multiple-ascending dose (MAD) part of this trial.

VTX002 (S1P1R Modulator)

VTX002 is a potent, oral and highly selective peripherally restricted S1P1R modulator with high selectivity for the S1P1 receptor that is ready to enter Phase 2 development. In a Phase 1 trial in healthy volunteers, VTX002 was well tolerated at all doses tested with no serious adverse events. In addition, VTX002 showed a robust, dose-dependent, steady-state reduction in ALC of up to 65%. Reduction in circulating ALCs is a well-established biomarker for S1P1-mediated diseases, and S1P1 signaling has been identified as a key regulator of lymphocyte migration from lymph nodes into circulation. The blockade of this axis is emerging as a promising therapeutic approach in controlling aberrant leukocyte migration into the mucosa in IBD, suggesting clinical potential in UC patients.

Based on these Phase 1 healthy volunteer data, we plan to initiate a Phase 2 randomized, placebo-controlled clinical trial in the second half of 2021 and believe that the trial may serve as the first of two pivotal trials required for registration along with an additional Phase 3 trial. In addition, we may conduct additional clinical trials for VTX002 in other relevant immunology indications.

VTX2735 and Preclinical NLRP3 Inhibitor Portfolio

Inflammasomes are multi-protein complexes that sense molecular hallmarks of infection or cellular injury and initiate an appropriate immune response. We plan to harness the therapeutic potential of innate immune modulation with an initial focus on the NLRP3 inflammasome, one of the most widely studied members of the inflammasome family.

NLRP3 releases interleukin (IL)-1β when activated. Aberrant NLRP3 activation is involved in a range of both acute and chronic inflammatory conditions. Although several biologics targeting the downstream cytokine IL-1β have been approved for treatment of autoimmune diseases (such as Cryopyrin-Associated Periodic Syndromes (CAPS), Familial Mediterranean Fever, Still's disease, and juvenile idiopathic arthritis), we believe direct targeting of NLRP3 with an oral agent may provide certain advantages as a therapeutic approach over currently approved biologics.

VTX2735 has demonstrated potent NLRP3 inhibition in cellular assays, potent *in vivo* pharmacodynamic activity in an animal model, and high oral bioavailability in multiple preclinical species. Preclinical safety and toxicology studies suggest that VTX2735 has a broad therapeutic window, which may allow attaining maximal target engagement in future human trials. We expect to submit an IND application for VTX2735 in the second half of 2021 and, if accepted, we intend to initiate a Phase 1 clinical trial in healthy volunteers.

Our Competitive Strengths

We believe our deep internal drug discovery and development expertise has enabled us to identify and advance multiple small molecule product candidates from preclinical studies into clinical trials in a rapid and efficient manner. Our extensive knowledge of the pathophysiology and biology of immunologic conditions informs our decision-making to advance the best scientific and clinical path to demonstrate pharmacological activity and proof-of-concept within an efficient timeframe and cost-effective budget. The infrastructure within our discovery and development capabilities includes all aspects of the drug discovery process, such as medicinal and process chemistry, computational chemistry, structural biology, and *in vitro* and *in vivo* pharmacology. Our approach to drug discovery and development allows us to work in a seamless and simultaneous manner, rather than in sequential fashion. In our TYK2 inhibitor program, for example, we initiated our Phase 1 trial in March 2021, representing a 25-month timeframe from lead identification to a first-in-human trial. We believe that our expertise will allow us to achieve similar development timelines and

milestones with our earlier stage preclinical programs while mitigating some of the risks usually associated with new product development.

The key elements of our approach to discovery and development include:

- An iterative lead optimization approach that utilizes rational and empirical drug design, allowing for rapid advancement of our lead compounds and delivering drug candidates with high non-clinical potency and selectivity for our immunology targets; and
- Relevant screening methods that utilize human cellular assays and human whole blood for our lead optimization assays, including a biomarker-driven approach. We believe that this approach offers the best and most relevant predictor of potency, efficacy and therapeutic window for our compounds in human clinical trials.

We have a diversified pipeline of promising product candidates, all of which target multi-billion-dollar commercial markets, which we believe, to date, are unsatisfied. We intend to leverage our drug discovery and development approach and expertise to advance this pipeline, and to apply our knowledge of the immunology market to augment and/or accelerate our pipeline through strategic partnerships.

Our Management Team, Executive Chair, Advisors and Investors

Our scientific and management team has decades of distinguished experience in the discovery and development of small molecule drugs, including within the immunology space, and a proven track record of advancing high-quality compounds into the clinic, some of which are successful commercial products.

Our founder and Chief Executive Officer, Raju Mohan, PhD, has over 30 years of experience in drug discovery and development, during which time he advanced 10 product candidates into the clinic for a broad range of disease indications. Dr. Mohan is an inventor of esaxerenone, which is approved and marketed as Minnebro. He started his career at Schering AG/Berlex Biosciences, Inc., followed by X-Ceptor Therapeutics, Inc., which was acquired by Exelixis, Inc. in 2004. In addition to Ventyx, he is the founder of multiple start-up biopharmaceutical companies, including Ralexar Biosciences, Inc., Akarna Therapeutics Ltd. (acquired by Allergan plc in 2016), Escalier Biosciences BV, Oppilan Pharma Ltd. (Oppilan), Zomagen Biosciences Ltd. (Zomagen) and Vimalan Biosciences, Inc. Our Chief Scientific Officer, John Nuss, PhD, has over 25 years of experience in drug discovery and development having advanced over 25 compounds into development, including three approved drugs: Cometriq (cabozantinib), Cotellic (cobimetinib), and Minnebro. He served in senior positions at Ferring Research Institute and Exelixis, Inc. Our Chief Financial Officer, Martin Auster, MD, most recently served as Managing Director, Biotechnology Analyst at Credit Suisse AG. Prior to Credit Suisse, he was a senior biotechnology analyst at UBS Securities LLC. Earlier, he served in senior executive positions at Ascendis Pharma A/S and United Therapeutics Corporation, and as a senior biotechnology analyst at Wachovia Securities and GLG Partners. Our Chief Business Officer, Christopher Krueger, JD, MBA, has over 20 years of operational experience in public and private biopharmaceutical companies. He most recently served as Chief Executive Officer of Oppilan and Chief Business Officer at Zomagen until their acquisitions by Ventyx Biosciences, Inc. in 2021. He previously served as the Chief Business Officer of Akarna Therapeutics Ltd. until its acquisition by Allergan plc in 2016 and the Chief Business Officer of Ardea Biosciences, Inc. prior to its acquisition by AstraZeneca plc.

Our board of directors is led by Executive Chair, Sheila Gujrathi, MD, a seasoned pharmaceutical executive who has successfully built and financed biotech companies, managed complex clinical and research stage pipelines, and led the advancement and approval of multiple novel small molecule and biologic therapeutics in immunology, inflammation and oncology therapeutic areas. Dr. Gujrathi is the co-founder and former Chief Executive Officer of Gossamer Bio, Inc. Prior to Gossamer, Dr. Gujrathi served as Chief Medical Officer of Receptos, Inc. (acquired by Celgene Corporation) and was responsible for the clinical development of Zeposia (ozanimod), which is approved for multiple sclerosis and UC. Prior to Receptos, Dr. Gujrathi served as Vice President of the Global Clinical Development Group in Immunology at Bristol-Myers Squibb Company (BMS), where she led late-stage clinical development and supported numerous global regulatory filings and approvals for Orencia® and Nulojix®. Prior to BMS, Dr. Gujrathi held roles in immunology, tissue growth and repair in the clinical development groups at Genentech, Inc., where she worked on Ocrevus®, Rituxan®, Xolair®, and a number of other programs across all stages of development and served as the Avastin® franchise team leader.

Our clinical and scientific advisors are world-renowned experts in scientific and clinical development aspects of our specific immunology targets and within the inflammatory and autoimmune diseases generally, and have

translational experience with human biomarkers of disease. Our Clinical and Scientific Advisory Board includes: William J. Sandborn, MD, Chief Medical Officer at Shoreline Biosciences, Inc.; James G. Krueger, MD, PhD, Director of the Milstein Medical Research Program and D. Martin Carter Professor in Clinical Investigation at The Rockefeller University; Alexa Kimball, MD, Chief Executive Officer and President of Harvard Medical Faculty Physicians at Beth Israel Deaconess Medical Center; Bruce Sands, MD, MS, the Dr. Burrill B. Crohn Professor of Medicine at the Icahn School of Medicine at Mount Sinai; Emma Guttman-Yassky, MD, PhD, System Chair of the Department of Dermatology and the Waldman Professor of Dermatology and Immunology at the Icahn School of Medicine at Mount Sinai; and, Luisa Salter-Cid, PhD, Chief Scientific Officer of Pioneering Medicines (a division of Flagship Pioneering) and former Chief Scientific Officer of Gossamer Bio, Inc. and Vice President and Head of Immunology, Small Molecule Immuno-Oncology, at BMS).

To date, we have raised over $114 million from leading life sciences investors, including venBio Partners, Third Point, RTW Investments, LP, Janus Henderson Investors, Wellington Management Company LLP, OrbiMed Advisors LLC, Surveyor Capital (a Citadel company), Farallon Capital Management, LLC, Vivo Capital, Logos Capital, Qiming Venture Partners USA, Cormorant Asset Management LLC, and New Science Ventures LLC.

Our Strategy

Our goal is to become a leader in developing differentiated, best-in-class and first-in-class product candidates in a rapid and efficient manner for the immunology market and, ultimately, to address well-established, yet unsatisfied, multi-billion-dollar commercial markets.

The three key elements to achieve this strategy include:

- ***Focusing on the identification and development of differentiated product candidates against high-value, validated immunology targets that address efficacy and safety limitations of currently approved drugs and those in development. Specifically, we will:***
  - Maximize the value of VTX958, our highly selective TYK2 inhibitor, by developing it across multiple inflammatory and autoimmune indications.
  - Rapidly advance VTX002, our selective S1P1R modulator through clinical development in UC.
  - Advance our portfolio of NLRP3 inhibitors, starting with VTX2735, into clinical development.
- ***Pursuing efficient and informed development of product candidates by fully leveraging the capabilities of our internal small molecule discovery engine and development infrastructure.***
- ***Entering into strategic partnerships that may expand and/or accelerate our programs to maximize worldwide commercial potential of our product candidates.***

Summary Risk Factors

Our business is subject to numerous risks and uncertainties that you should consider before investing in us. These risks are described more fully in the section titled “Risk Factors” in this prospectus. These risks include, but are not limited to, the following:

- We have a history of operating losses and have incurred significant losses since our inception. We expect to continue to incur significant losses and we may never be profitable;
- Our limited operating history, and the biotechnology industry in which we operate, make it difficult to evaluate our business plan and our prospects;
- Our business depends entirely on the success of our product candidates and we cannot guarantee that these product candidates will successfully complete development, receive regulatory approval, or be successfully commercialized. If we are unable to develop, receive regulatory approval for, and ultimately successfully commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed;
- Our clinical trials may fail to demonstrate adequately the safety and efficacy of our product candidates, which would prevent or delay regulatory approval and commercialization;
- Clinical development involves a lengthy and expensive process with an uncertain outcome, and results of early, smaller-scale studies and clinical trials with a single or few clinical trial sites may not be predictive of eventual safety or effectiveness in large-scale pivotal clinical trials across multiple clinical trial sites. We may encounter substantial delays in clinical trials, or may not be able to conduct or complete clinical trials on the expected timelines, if at all;
- We face significant competition from other biotechnology and pharmaceutical companies;

- We may use our limited financial and human resources to pursue a particular type of treatment, or treatment for a particular type of disease, and fail to capitalize on programs or treatments of other types of diseases that may be more profitable or for which there is a greater likelihood of success;
- We may develop product candidates in combination with other therapies, which exposes us to additional risks and could result in our products, even if approved, being removed from the market or being less successful commercially;
- It may take longer and cost more to complete our clinical trials than we project, or we may not be able to complete them at all;
- The FDA regulatory approval process is lengthy, time-consuming and unpredictable, and we may experience significant delays in the clinical development and regulatory approval of our product candidates; and
- If we are unable to obtain and maintain sufficient intellectual property protection for our product candidates, or if the scope of the intellectual property protection is not sufficiently broad, we may not be able to compete effectively or operate profitably.

Corporate Information

We were incorporated in Delaware on November 21, 2018. Our principal executive offices are located at 662 Encinitas Blvd, Suite 250, Encinitas, CA 92024. Our telephone number is (760) 593-4832. Our website address is http://www.ventyxbio.com. Information contained on, or that can be accessed through, the website is not incorporated by reference into this prospectus and the inclusion of our website address in this prospectus is an inactive textual reference only.

We use Ventyx, the Ventyx logo and other marks as trademarks in the United States and other countries. This prospectus contains references to our trademarks and service marks and to those belonging to other entities. Solely for convenience, trademarks and trade names referred to in this prospectus, including logos, artwork and other visual displays, may appear without the ® or ™ symbols, but such references are not intended to indicate in any way that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks and trade names. We do not intend our use or display of other entities' trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, any other entity.

Implications of Being an Emerging Growth Company and a Smaller Reporting Company

We qualify as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, as amended, or the JOBS Act. An emerging growth company may take advantage of relief from certain reporting requirements and other burdens that are otherwise applicable generally to public companies. These provisions include:

- reduced obligations with respect to financial data, including presenting only two years of audited consolidated financial statements and only two years of selected financial data;
- an exception from compliance with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act;
- reduced disclosure about our executive compensation arrangements in our periodic reports, proxy statements and registration statements; and
- exemptions from the requirements of holding non-binding advisory votes on executive compensation or golden parachute arrangements.

In addition, Section 107 of the JOBS Act provides that an emerging growth company can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended, or the Securities Act, for complying with new or revised accounting standards. In other words, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. Section 107 of the JOBS Act provides that any decision to opt out of the extended transition period for complying with new or revised accounting standards is irrevocable. We have elected to use this extended transition period under the JOBS Act.

We may take advantage of these provisions for up to five years or until such earlier time when we no longer qualify as an emerging growth company. We will cease to be an emerging growth company upon the earliest of (1) the end of the fiscal year following the fifth anniversary of this offering; (2) the last day of the fiscal year

during which our annual gross revenues are $1.07 billion or more; (3) the date on which we have, during the previous three-year period, issued more than $1.0 billion in non-convertible debt securities; and (4) the end of any fiscal year in which the market value of our common stock held by non-affiliates exceeded $700.0 million as of the end of the second quarter of that fiscal year. We may choose to take advantage of some or all of these reduced reporting burdens.

In addition, we are also a “smaller reporting company” because the market value of our stock held by non-affiliates plus the proposed aggregate amount of gross proceeds to us as a result of this offering is less than $700 million as of June 30, 2019 and our annual revenue was less than $100 million during the fiscal year ended December 31, 2019. We may continue to be a smaller reporting company after this offering in any given year if either (i) the market value of our stock held by non-affiliates is less than $250 million as of June 30 in the most recently completed fiscal year or (ii) our annual revenue is less than $100 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700 million as of June 30 in the most recently completed fiscal year. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

For risks related to our status as an emerging growth company and a smaller reporting company, see the disclosure in the section titled “Risk Factors.”

The Offering

Common stock offered	shares
Underwriters' option to purchase additional shares of common stock	shares
Common stock to be outstanding after this offering	shares (or shares if the underwriters exercise in full their option to purchase additional shares)
Use of proceeds	We estimate that the net proceeds to us from this offering will be approximately $ million (or approximately $ million if the underwriters exercise in full their option to purchase additional shares) assuming an initial offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. We currently expect to use all of the net proceeds from this offering, together with our existing cash and cash equivalents, to fund the clinical development of VTX958, VTX002 and VTX2735, the preclinical development of other programs, research activities and working capital and other general corporate purposes. We may also use a portion of the net proceeds to acquire, license, and invest in complementary products, technologies or businesses; however, we currently have no agreements or commitments to complete any such transaction. See the section titled "Use of Proceeds."
Risk factors	See the section titled "Risk Factors" and other information included in this prospectus for a discussion of factors you should carefully consider before deciding to invest in shares of our common stock.
Proposed Nasdaq trading symbol	"VTYX"

The number of shares of our common stock to be outstanding immediately after this offering is based on shares of our common stock outstanding as of June 30, 2021 (including the automatic conversion of all of our shares of convertible preferred stock outstanding as of June 30, 2021 into an aggregate of shares of our common stock immediately prior to the completion of this offering), which includes 1,646,168 shares outstanding that are subject to our right to repurchase as of such date, and excludes the following:

- shares of common stock issuable upon exercise of options to purchase shares of our common stock outstanding as of June 30, 2021, with a weighted-average exercise price of $ per share;
- shares of common stock issuable upon exercise of options to purchase shares of our common stock that were granted after June 30, 2021, with a weighted-average exercise price of $ per share;
- shares of common stock reserved for future issuance under our 2019 Equity Incentive Plan, as amended (the 2019 Plan), as of June 30, 2021, which shares will be added to the shares to be reserved under our 2021 Equity Incentive Plan (the 2021 Plan) upon its effectiveness; and
- shares of common stock reserved for future issuance under our 2021 Plan, which will become effective on the business day immediately prior to the date of effectiveness of the registration statement of which this prospectus forms a part, as well as any automatic increases in the number of shares of common stock reserved for future issuance under this plan.

Except as otherwise indicated, all information in this prospectus assumes:

- a 1-for- reverse stock split of our capital stock, which was effected on , 2021;
- no exercise of the outstanding options or warrants referred to above;
- no exercise by the underwriters of their option to purchase additional shares;

- the automatic conversion of all outstanding shares of our convertible preferred stock as of June 30, 2021 into an aggregate of shares of our common stock, which will occur immediately prior to the completion of this offering; and
- the adoption, filing and effectiveness of our amended and restated certificate of incorporation and the adoption of our amended and restated bylaws, each of which will occur immediately prior to the completion of this offering.

Summary Consolidated Financial Data

The following tables summarize our consolidated financial data for the periods and as of the dates indicated. We have derived the statements of operations and comprehensive loss data for the years ended December 31, 2019 and 2020 (except for the pro forma net loss per share and the pro forma share information) from our audited financial statements and related notes included elsewhere in this prospectus. We derived the statement of operations data for the six months ended June 30, 2020 and June 30, 2021 and the balance sheet data as of June 30, 2021 from the unaudited interim financial statements included elsewhere in this prospectus. The unaudited interim financial statements have been prepared on the same basis as our annual audited financial statements and, in the opinion of management, reflect all adjustments, which include only normal, recurring adjustments, that are necessary to present fairly the unaudited interim financial statements. Our historical results are not necessarily indicative of results that may be expected in the future, and the results for the six months ended June 30, 2021, are not necessarily indicative of results that may be expected for the full year or any other period. You should read the following summary consolidated financial data together with our financial

statements and the related notes included elsewhere in this prospectus and the information in the section titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations.”

	YEAR ENDED DECEMBER 31,		SIX MONTHS ENDED JUNE 30,	
	2019	2020	2020	2021
			(unaudited)	
	(in thousands, except share and per share data)			
Consolidated Statements of Operations and Comprehensive Loss Data:				
Operating expenses:				
Research and development (includes related party amounts of $1,374, $965 $647 and $462, respectively)	$ 3,552	$ 6,366	$ 3,069	$ 34,112
General and administrative (includes related party amounts of $296, $400, $221 and $116, respectively)	628	684	305	2,422
Total operating expenses	4,180	7,050	3,374	36,534
Loss from operations	(4,180)	(7,050)	(3,374)	(36,534)
Other expense:				
Other expense	1	1	—	44
Interest expense - related party	146	358	111	99
Change in fair value of notes and derivative - related party	—	20,765	831	11,051
Change in fair value of Series A tranche liability	—	—	—	5,476
Total other expense	147	21,124	942	16,670
Net loss	$ (4,327)	$ (28,174)	$ (4,316)	$ (53,204)
Deemed dividend	—	—	—	(1,552)
Net loss attributable to common stockholders	$ (4,327)	$ (28,174)	$ (4,316)	(54,756)
Net loss	$ (4,327)	$ (28,174)	$ (4,316)	$ (53,204)
Foreign currency translation	—	—	—	12
Comprehensive loss	$ (4,327)	$ (28,174)	$ (4,316)	$ (53,216)
Net loss per share attributable to common stockholders, basic and diluted (1)	$ (0.27)	$ (1.48)	$ (0.23)	$ (1.80)
Shares used to compute basic and diluted net loss per common share (1)	15,897,424	19,022,848	18,721,146	29,607,406
Pro forma net loss per share attributed to common stockholders, basic and diluted (unaudited) (2)				
Shares used to compute pro forma basic and diluted net loss per common share (2)				

(1) For the calculation of our basic and diluted net loss per share, basic and diluted pro forma net loss per share and weighted-average number of shares used in the computation of the per share amounts, see Note 2 to our financial statements included elsewhere in this prospectus.

(2) The calculations for the unaudited pro forma net loss per common share, basic and diluted, and the pro forma weighted average shares of common stock outstanding, basic and diluted, assume the conversion of all our outstanding shares of convertible preferred stock into shares of our common stock, as if the conversion had occurred at the beginning of the period presented, or the issuance date, if later.

	AS OF JUNE 30, 2021		
	ACTUAL	PRO FORMA[1]	PRO FORMA AS ADJUSTED[2][3]
		(in thousands) (unaudited)	
Consolidated Balance Sheet Data			
Cash and cash equivalents	$ 102,788		
Working capital (4)	$ 96,964		
Total assets	$ 105,916		
Series A convertible preferred shares	$ 116,279		
Series A-1 convertible preferred shares	$ 57,437		
Accumulated deficit	$ 87,257		
Total stockholders' (deficit) equity	$ 75,864		

(1) The pro forma consolidated balance sheet data gives effect to: (i) the automatic conversion of all outstanding shares of our convertible preferred stock as of June 30, 2021 into an aggregate of 299,369,811 shares of our common stock, which will occur immediately prior to the completion of this offering, and (ii) the adoption, filing and effectiveness of our amended and restated certificate of incorporation, which will occur immediately prior to the completion of this offering.

(2) The pro forma as adjusted consolidated balance sheet data gives effect to: (i) the pro forma adjustments described in footnote (1) above, and (ii) the issuance and sale of shares of common stock in this offering at the assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

(3) Each $1.00 increase or decrease in the assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase or decrease, as applicable, the pro forma as adjusted amount of each of cash and cash equivalents, total assets, and total stockholders' (deficit) equity by approximately $ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase or decrease of 1.0 million shares in the number of shares offered by us at the assumed initial public offering price after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us would increase or decrease, as applicable, each of cash and cash equivalents, total assets, and total stockholders' (deficit) equity by approximately $ million. The pro forma information discussed above is illustrative only and will be adjusted based on the actual initial public offering price and other terms of our initial public offering determined at pricing.

(4) We define working capital as current assets less current liabilities. See our consolidated financial statements and the related notes included elsewhere in this prospectus for further details regarding our current assets and current liabilities.

RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as all other information included in this prospectus, including our consolidated financial statements and the related notes and the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" before you decide to purchase shares of our common stock. If any of the following risks actually occurs, our business, financial condition, results of operations, prospects and ability to accomplish our strategic objectives could be materially harmed. As a result, the trading price of our common stock could decline and you could lose all or part of your investment. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations and the market price of our common stock.

Risks Related to Our Business

We have a history of operating losses and have incurred significant losses since our inception. We expect to continue to incur significant losses and we may never be profitable.

Since our inception in November 2018, we have incurred significant operating losses, we have not generated any revenue from operations to date and have financed our operations primarily through private placements of our convertible preferred stock and convertible debt instruments. We do not have any products approved for commercial sale or for which marketing approval has been sought. As of December 31, 2020, we had an accumulated deficit of $32.5 million. In addition, during the year ended December 31, 2020, we incurred a net loss of $28.1 million, compared with a net loss of $4.3 million for the year ended December 31, 2019. As of June 30, 2021, we had an accumulated deficit of $53.2 million. We do not expect to generate any meaningful revenue from product sales, unless and until we successfully complete development and obtain marketing approval for one or more of our product candidates, which we do not expect to happen for at least the next several years, if ever. We expect to incur significant and increasing operating losses in the future. The operating losses we incur may fluctuate significantly from quarter to quarter and year to year, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance.

Our ability to achieve profitability in the future is dependent upon obtaining regulatory approvals for our products and successfully commercializing our products alone or with third parties. However, our operations may not be profitable even if one or more of our product candidates under development are successfully developed, approved and thereafter commercialized.

Our limited operating history, and the biotechnology industry in which we operate, make it difficult to evaluate our business plan and our prospects.

We are an early-stage company, we were founded in November 2018 and have a limited operating history. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We have only a limited operating history on which a decision to invest in our company can be based and against which we can test the plans and assumptions in our business plan, and investors therefore cannot evaluate the likelihood of our success. The future of our company is dependent upon our ability to implement our business plan, as that business plan may be modified from time to time by our management and board of directors.

We face the problems, expenses, difficulties, complications and delays normally associated with a pre-commercial biotechnology company, many of which are beyond our control. Accordingly, our prospects should be considered in light of the risks, expenses and difficulties frequently encountered in the establishment of a new business developing product candidates in an industry that is characterized by a number of market entrants and intense competition. Because of our size and limited resources, we may not possess the ability to successfully overcome many of the risks and uncertainties frequently encountered by pre-commercial companies involved in the rapidly evolving field of immunology. If we do not address these risks successfully, our business will suffer. In addition, as a new business, we may encounter other unforeseen expenses, difficulties, complications, delays, and other known and unknown factors. Even if our research and development efforts are successful, we may also face the risks associated with the transition from development to commercialization of new products. We may not be successful in such a transition. There can be no assurance that we will be successful in developing our business. If we do not adequately address these risks and difficulties or successfully make such a transition, our business will suffer.

Our business depends entirely on the success of our product candidates and we cannot guarantee that these product candidates will successfully complete development, receive regulatory approval, or be successfully commercialized. If we are unable to develop, receive regulatory approval for, and ultimately successfully commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed.

We currently have no products approved for commercial sale or for which regulatory approval to market has been sought. We have invested a significant portion of our efforts and financial resources in the development of our lead product candidates targeting S1P1R, TYK2 and NLRP3, each of which is still in early stages of clinical development, and expect that we will continue to invest heavily in these product candidates, as well as in any future product candidates we may develop. Our business depends entirely on the successful development, regulatory approval and commercialization of our product candidates, each of which may never occur. Our ability to generate revenues, which we do not expect will occur for many years, if ever, is substantially dependent on our ability to develop, obtain regulatory approval for, and then successfully commercialize our product candidates, which may never occur.

Our product candidates will require substantial additional clinical and non-clinical development time, regulatory approval, commercial manufacturing arrangements, establishment of a commercial organization, significant marketing efforts, and further investment before we can generate any revenue from product sales. We currently generate no revenue and we may never be able to develop or commercialize any products. We cannot assure you that we will meet our timelines for our current or future clinical trials, which may be delayed or not completed for a number of reasons, including the negative impact of the COVID-19 pandemic. Our product candidates are susceptible to the risks of failure inherent at any stage of product development, including the appearance of unexpected adverse events or failure to achieve primary endpoints in clinical trials.

Even if our product candidates are successful in clinical trials, we are not permitted to market or promote any of our product candidates before we receive regulatory approval from the U.S. Food and Drug Administration, or the FDA, or comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our product candidates or regulatory approval that will allow us to successfully commercialize our product candidates. If we do not receive FDA or comparable foreign regulatory approval with the necessary conditions to allow commercialization, we will not be able to generate revenue from those product candidates in the United States or elsewhere in the foreseeable future, or at all. Any significant delays in obtaining approval for and commercializing our product candidates will have a material adverse impact on our business and financial condition.

We have not previously submitted a New Drug Application, or NDA, for any small molecule product candidates or similar marketing application to the FDA or comparable foreign regulatory authorities, for any product candidate, and we cannot be certain that our current or any future product candidates will be successful in clinical trials or receive regulatory approval. Furthermore, although we do not expect to submit an NDA with comparisons to existing or more established therapies and we do not expect the FDA to base its determination with respect to product approval on such comparisons, the FDA may factor these comparisons into its decision whether to approve our product candidates. The FDA may also consider its approvals of competing products, which may alter the treatment landscape concurrently with their review of our NDA filings, and which may lead to changes in the FDA's review requirements that have been previously communicated to us and our interpretation thereof, including changes to requirements for clinical data or clinical study design. Such changes could delay approval or necessitate withdrawal of our NDA filings.

If approved for marketing by applicable regulatory authorities, our ability to generate revenues from our product candidates will depend on our ability to:

- price our product candidates competitively such that third-party and government reimbursement leads to broad product adoption;
- prepare a broad network of clinical sites for administration of our product;
- create market demand for our product candidates through our own marketing and sales activities, and any other arrangements to promote these product candidates that we may otherwise establish;
- receive regulatory approval for the targeted patient population(s) and claims that are necessary or desirable for successful marketing;
- effectively commercialize any of our product candidates that receive regulatory approval;

- manufacture product candidates through contract manufacturing organizations, or CMOs, or in our own, or our affiliates', manufacturing facility in sufficient quantities and at acceptable quality and manufacturing cost to meet commercial demand at launch and thereafter;
- establish and maintain agreements with wholesalers, distributors, pharmacies, and group purchasing organizations on commercially reasonable terms;
- obtain, maintain, protect and enforce patent and other intellectual property protection and regulatory exclusivity for our product candidates;
- maintain compliance with applicable laws, regulations, and guidance specific to commercialization including interactions with health care professionals, patient advocacy groups, and communication of health care economic information to payors and formularies;
- achieve market acceptance of our product candidates by patients, the medical community, and third-party payors;
- achieve appropriate reimbursement for our product candidates;
- maintain a distribution and logistics network capable of product storage within our specifications and regulatory guidelines, and further capable of timely product delivery to commercial clinical sites;
- effectively compete with other therapies or competitors; and
- assure that our product candidates will be used as directed and that additional unexpected safety risks will not arise.

It may take longer and cost more to complete our clinical trials than we project, or we may not be able to complete them at all.

For budgeting and planning purposes, we have projected the date for the commencement of future trials, and continuation and completion of our ongoing clinical trials. However, a number of factors, including scheduling conflicts with participating clinicians and clinical institutions, and difficulties in identifying and enrolling patients who meet trial eligibility criteria, may cause significant delays. We may not commence or complete clinical trials involving any of our products as projected or may not conduct them successfully.

Our ability to enroll or treat patients in our clinical trials, or the duration or costs of those clinical trials, could be affected by multiple factors, including, preliminary clinical results, which may include efficacy and safety results, but may not be reflected in the final analyses of these clinical trials. Depending on the outcome of our clinical trials, we may need to conduct one or more follow-up or supporting clinical trials in order to develop our products for FDA approval. Many companies in the biotechnology and pharmaceutical industries have suffered significant setbacks in late-stage clinical trials even after achieving positive results in earlier development, and we cannot be certain that we will not face such setbacks.

Furthermore, the timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the study until its conclusion, including the ability of us or our collaborators to conduct clinical trials under the constraints of the COVID-19 pandemic. In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Accordingly, we cannot guarantee that the trial will progress as planned or as scheduled. Delays in enrollment may result in increased costs or may affect the timing or outcome of our ongoing clinical trial and planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our product candidates.

Our clinical trials may fail to demonstrate adequately the safety and efficacy of our product candidates, which would prevent or delay regulatory approval and commercialization.

The clinical trials of our product candidates are, and, if approved, the manufacturing and marketing of our products will be, subject to extensive and rigorous review and regulation by numerous government authorities in the United States and in other countries where we intend to test and market our product candidates. Before obtaining regulatory approvals for the commercial sale of any of our product candidates, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that our product candidates are both safe and effective for use in each target indication. For our small molecule product candidates, we will need to demonstrate that they are safe and effective for their target indications and must demonstrate an adequate risk versus benefit profile in its intended patient population and for its intended use. Regulatory authorities may ultimately disagree with our chosen endpoints or may find that our clinical studies or clinical study results do not support product approval. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process.

There is typically an extremely high rate of attrition from the failure of product candidates proceeding through clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy profile despite having progressed through preclinical studies and initial clinical trials. Preclinical studies may also reveal unfavorable product candidate characteristics, including safety concerns. Many companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. Most product candidates that begin clinical trials are never approved by regulatory authorities for commercialization. In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the clinical trial protocols and the rate of dropout among clinical trial participants. Our current and future clinical trial results may not be successful. Moreover, should there be a flaw in a clinical trial or cross-site variation that are not properly addressed, it may not become apparent until the clinical trial is well advanced or until data from different sites become available. For example, our clinical trials are conducted at multiple sites in different geographies, with different levels of experience and expertise by medical professionals, and these professionals may make mistakes or introduce site-specific variation that could have an impact on the clinical data or on clinical trials by disqualifying patients or impacting patient ability to continue in a study.

Clinical development involves a lengthy and expensive process with an uncertain outcome, and results of early, smaller-scale studies and clinical trials with a single or few clinical trial sites may not be predictive of eventual safety or effectiveness in large-scale pivotal clinical trials across multiple clinical trial sites. We may encounter substantial delays in clinical trials, or may not be able to conduct or complete clinical trials on the expected timelines, if at all.

Before obtaining regulatory approvals for the commercial sale of our product candidates, we must demonstrate through lengthy, complex and expensive nonclinical studies and clinical trials that our product candidates are both safe and effective for each target indication. Preclinical and clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the preclinical study and clinical trial processes, and, because our product candidates are in an early stage of development, there is a high risk of failure and we may never succeed in developing marketable products. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. Although product candidates may demonstrate promising results in preclinical studies and early clinical trials, they may not prove to be safe or effective in subsequent clinical trials. For example, testing on animals occurs under different conditions than testing in humans and therefore, the results of animal studies may not accurately predict safety and effectiveness in humans. There is typically an extremely high rate of attrition from the failure of product candidates proceeding through preclinical studies and clinical trials.

Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy profile despite having progressed through preclinical studies and initial clinical trials. Likewise, early, smaller-scale studies and clinical trials with a single or few clinical trial sites may not be predictive of eventual safety or effectiveness in large-scale pivotal clinical trials across multiple clinical trial sites. Even if data from a pivotal clinical trial are positive, regulators may not agree that such data are sufficient for approval and may require that we conduct additional clinical trials, which could materially delay our anticipated development timelines, require additional funding for such additional clinical trials, and adversely impact our business. Most product candidates that commence preclinical studies and clinical trials are never approved as products.

In some instances, there can be significant variability in safety or efficacy results between different preclinical studies and clinical trials of the same product candidate due to numerous factors, including changes in clinical trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the clinical trial protocols and the rate of dropout among clinical trial participants. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects. In such an event, our clinical trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. Drug-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the clinical trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

Additionally, some of the clinical trials we conduct in the future may be open-label in study design and may be conducted at a limited number of clinical sites on a limited number of patients. An “open-label” clinical trial is one where both the patient and investigator know whether the patient is receiving the investigational product

candidate or either an existing approved drug or placebo. Most typically, open-label clinical trials test only the investigational product candidate and sometimes may do so at different dose levels. Open-label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open-label clinical trials are aware when they are receiving treatment. Open-label clinical trials may be subject to a “patient bias” where patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. In addition, open-label clinical trials may be subject to an “investigator bias” where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the institutional review boards, or IRBs, of the institutions in which such clinical trials are being conducted, by a data safety monitoring board for such clinical trial or by the FDA or comparable foreign regulatory authorities. Clinical trials can be delayed or terminated for a variety of reasons, including delays or failures related to:

- the FDA or comparable foreign regulatory authorities disagreeing as to the trial design or implementation of our clinical trials;
- changes in governmental regulations, including FDA policies and regulatory requirements for clinical trials and standards or data requirements for pharmaceutical approval or administrative actions;
- delays in our ability to commence a clinical trial;
- reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- obtaining IRB approval at each clinical trial site;
- recruiting an adequate number of suitable patients to participate in a clinical trial;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate;
- having subjects complete a clinical trial or return for post-treatment follow-up;
- clinical trial sites deviating from clinical trial protocol or dropping out of a clinical trial;
- failure to demonstrate a clinical benefit from using a product candidate;
- addressing subject safety concerns that arise during the course of a clinical trial;
- adding a sufficient number of clinical trial sites; or
- obtaining sufficient product supply of product candidate for use in preclinical studies or clinical trials from third-party suppliers.

Further, conducting clinical trials in foreign countries can present additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled patients in foreign countries to adhere to clinical protocol as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, as well as political and economic risks relevant to such foreign countries.

Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authority may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA or comparable foreign regulatory authority may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or comparable foreign regulatory authority, as the case may be, and may ultimately lead to the denial of marketing approval of one or more of our product candidates.

If we experience delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. Moreover, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues.

If the results of our current and future clinical trials are inconclusive with respect to the efficacy of our product candidates, if we do not meet the clinical endpoints with statistical and clinically meaningful significance, or if there are safety concerns associated with our product candidates, we may:

- incur unplanned costs;
- be delayed in or prevented from obtaining marketing approval for our product candidates;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings including boxed warnings;
- be subject to changes in the way the product is administered;
- be required to perform additional clinical trials to support approval or be subject to additional post-marketing testing requirements;
- have regulatory authorities withdraw their approval of the product or impose restrictions on its distribution in the form of a modified risk evaluation and mitigation strategy, or REMS;
- be subject to the addition of labeling statements, such as warnings or contraindications;
- be sued; or
- experience damage to our reputation.

If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities and receipt of necessary marketing approvals could be delayed or otherwise adversely affected.

The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients, who remain in the trial until its conclusion. We may experience difficulties or delays in patient enrollment in our clinical trials for a variety of reasons, including:

- the size and nature of the patient population;
- The number of ongoing and planned clinical trials in the indications that we are pursuing, such as UC and CD, which have very slow enrollment rates;
- the severity of the disease under investigation;
- the patient eligibility criteria defined in the protocol, including biomarker-driven identification and/or certain highly-specific criteria related to stage of disease progression, which may limit the patient populations eligible for our clinical trials to a greater extent than competing clinical trials for the same indication that do not have biomarker-driven patient eligibility criteria;
- the size of the study population required for analysis of the trial's primary or secondary endpoints;
- the proximity of patients to trial sites;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- the efforts to facilitate timely enrollment in clinical trials and the effectiveness of recruiting publicity;
- the patient referral practices of physicians;
- physicians' willingness to screen their patients for biomarkers to indicate which patients may be eligible for enrollment in our clinical trials;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate or enrollment in these clinical trials may be slower than we anticipate, potentially affecting our timelines for approval of our product candidates;
- patients that enroll in our clinical trials may misrepresent their eligibility or may otherwise not comply with the clinical trial protocol, resulting in the need to drop such patients from the clinical trial, increase the needed enrollment size for the clinical trial or extend the clinical trial's duration;
- clinical investigators enrolling patients who do not meet the enrollment criteria, requiring the inclusion of additional patients in the clinical trial;
- clinicians' and patients' perceptions as to the potential advantages and side effects of the product candidate being studied in relation to other available therapies, including any new drugs or treatments that may be approved for the indications we are investigating;
- approval of new indications for existing therapies or approval of new therapies in general;
- our contracted clinical sites' or investigators' ability to obtain and maintain patient consents;
- amendments to our clinical protocols, which may affect enrollment in, or results of, our clinical trials, including amendments we have made to further define the patient population to be studied;

- the impact of the current COVID-19 pandemic or other material adverse events, which may affect the conduct of a clinical trial, including by slowing potential enrollment or reducing the number of eligible patients for clinical trials; and
- the risk that patients enrolled in clinical trials will not complete a clinical trial, return for post-treatment follow-up, or follow the required study procedures. For instance, patients, including patients in any control groups, may withdraw from the clinical trial if they are not experiencing improvement in their underlying disease or condition. Withdrawal of patients from our clinical trials may compromise the quality of our data.

In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Because the number of qualified clinical investigators is limited, we may need to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites. Moreover, because our product candidates represent a departure from more commonly used treatments for inflammatory diseases and autoimmune disorders, potential patients and their doctors may be inclined to use conventional therapies rather than enroll patients in any future clinical trial. Additionally, patients, including patients in any control groups, may withdraw from the clinical trial if they are not experiencing improvement in their underlying disease or condition. Withdrawal of patients from our clinical trials may compromise the quality of our data.

Even if we are able to enroll a sufficient number of patients in our clinical trials, delays in patient enrollment or small population size may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these clinical trials and adversely affect our ability to advance the development of our product candidates.

Interim, initial, "top-line" and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose preliminary or top-line data from our preclinical studies and clinical trials, which are based on preliminary analyses of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular preclinical study or clinical trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the top-line or preliminary results that we report may differ from future results of the same studies or trials, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, top-line data should be viewed with caution until the final data are available.

From time to time, we may also disclose interim data from our preclinical studies and clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available or as patients from our clinical trials continue other treatments for their disease. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and could have a material adverse effect on the success of our business. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. If the interim, top-line or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, results of operations, prospects or financial condition. Further, disclosure of interim, top-line or preliminary data by us or by our competitors could result in volatility in the price of our common stock after this offering.

We face significant competition from other biotechnology and pharmaceutical companies.

Competition in the treatment of inflammatory diseases and autoimmune disorders is intense and is accentuated by the rapid pace of technological development. Research and discoveries by others may result in breakthroughs which may render our product candidates obsolete even before they are approved or generate any revenue. There are products that are approved and currently under development by others that could compete with the product candidates that we are developing. Our competitors may:

- develop safer, more convenient or more effective therapeutic products;
- develop therapeutic products that are less expensive or have better reimbursement from private or public payors;
- reach the market more rapidly, reducing the potential sales of our products; or
- establish superior proprietary positions.

Due to the promising clinical therapeutic effect of competitor therapies in clinical trials, we anticipate substantial direct competition from other organizations developing treatments for inflammatory diseases and autoimmune disorders, such as psoriasis, UC and Crohn's disease. In particular, we expect to compete with other new therapies for our lead indications developed by companies such as BMS and others. Many of these companies and our other current and potential competitors have substantially greater research and development capabilities and financial, scientific, regulatory, manufacturing, marketing, sales, human resources and experience than we do. Many of our competitors have several therapeutic products that have already been developed, approved and successfully commercialized, or are in the process of obtaining regulatory approval for their therapeutic products in the United States and internationally. Our competitors may obtain regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in competitors establishing a strong market position before we are able to enter the market.

Universities and public and private research institutions in the United States. and Europe are also potential competitors. While these universities and public and private research institutions primarily have educational objectives, they may develop proprietary technologies that lead to other FDA approved therapies or that secure patent protection that we may need for the development of our product candidates and that can be licensed or sold to other parties, including our competitors.

We are developing our lead product candidates, VTX958, VTX002 and VTX2735, for the treatment of inflammatory diseases and autoimmune disorders, such as psoriasis, UC and Crohn's disease. Currently, there are numerous companies that are developing various alternate treatments for these indications. With respect to VTX958, if approved, it would compete with injected biologic therapies and non-injectable systemic therapies. In addition, we are aware of several companies with product candidates in development for the treatment of patients with psoriasis, including deucravacitinib, which is an oral TYK2 inhibitor being developed by BMS. With respect to VTX002, if approved, it would compete with a number of companies developing product candidates as well as Zeopsia (ozanimod), which is an S1PR modulator marketed by BMS. With respect to VTX2735, we are aware of several other NLRP3 inhibitors in clinical or preclinical development, including Inzomelid and Somalix being developed by Roche. Accordingly, our lead product candidates will face significant competition from multiple companies. Even if we obtain regulatory approval for our lead product candidates, the availability and price of our competitors' products could limit the demand and the price we are able to charge for our products. We may not be able to implement our business plan if the acceptance of our products is inhibited by price competition or the reluctance of physicians to switch from other methods of treatment to our product, or if physicians switch to other new therapies, drugs or biologic products or choose to reserve our product for use in limited circumstances.

In addition, we could face litigation or other proceedings with respect to the scope, ownership, validity and/or enforceability of our patents or other intellectual property relating to our competitors' products, and our competitors may allege that our product candidates infringe, misappropriate or otherwise violate their intellectual property. See "—Risks Related to Intellectual Property."

Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

We have limited experience as a company conducting clinical trials and have relied and will rely on third parties and related parties to conduct our preclinical studies and clinical trials. Any failure by a third party, related party, or by us to conduct the clinical trials according to Good Clinical Practice and Good Manufacturing Practice, and in a timely manner may delay or prevent our ability to seek or obtain regulatory approval for or commercialize our product candidates.

We expect to rely on medical institutions, academic institutions or contract research organizations, or CROs, to conduct, supervise or monitor some or all aspects of clinical trials involving our product candidates. We will have less control over the timing and other aspects of these clinical trials than if we conducted them entirely on our own. If we fail to commence or complete, or experience delays in, any of our planned clinical trials, our stock price and our ability to conduct our business as currently planned could be harmed.

We have a limited history of conducting clinical trials and have no experience as a company in filing and supporting the applications necessary to gain marketing approvals. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety or efficacy for that indication. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities and clinical trial sites by, applicable regulatory authorities.

Large-scale clinical trials require significant financial and management resources, and reliance on third-party clinical investigators, CROs, CMOs, partners or consultants. Relying on third-party clinical investigators, CROs or CMOs may force us to encounter delays and challenges that are outside of our control. We may not be able to demonstrate sufficient comparability between products manufactured at different facilities to allow for inclusion of the clinical results from patients treated with products from these different facilities, in our product registrations. Further, our CMOs may not be able to manufacture our product candidates or otherwise fulfill their obligations to us because of interruptions to their business, including the loss of their key staff or interruptions to their raw material supply.

Our reliance on these third parties for development activities will reduce our control over these activities. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable trial protocol and legal, regulatory and scientific standards, and our reliance on the CROs, clinical trial sites, and other third parties does not relieve us of these responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the clinical trial and for ensuring that our preclinical studies are conducted in accordance with GCP, as appropriate. Moreover, the FDA and comparable foreign regulatory authorities require us to comply with Good Clinical Practice, or GCP, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Regulatory authorities enforce these requirements through periodic inspections (including pre-approval inspections once an NDA is filed with the FDA) of trial sponsors, clinical investigators, trial sites and certain third parties including CMOs and CROs. If we, our CROs, clinical trial sites, or other third parties fail to comply with applicable GCP or other regulatory requirements, we or they may be subject to enforcement or other legal actions, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations.

Our clinical trials must be conducted with product candidates that were produced under current Good Manufacturing Practices, or cGMP, regulations. Our failure to comply or our CMOs' failure to comply with these cGMP regulations may require us to repeat clinical trials, which would delay the regulatory approval process. We also are required to register certain clinical trials and post the results of certain completed clinical trials on a government sponsored database, ClinicalTrials.gov, within specified timeframes. Failure to do so could result in enforcement actions and adverse publicity.

We also rely on third parties other than our CMOs to manufacture, package, label and ship our product candidates for the clinical trials that we conduct. We may also find that the manufacture of our product candidates is more difficult than anticipated, resulting in an inability to produce a sufficient amount of our product candidates for our clinical trials or, if approved, commercial supply. Moreover, because of the complexity and novelty of our manufacturing process, there are only a limited number of manufacturers who have the capability of producing our product candidates. Should any of our contract manufacturers no longer produce our product candidates, it may take us significant time to find a replacement, if we are able to find a replacement at all. Any performance failure on the part of these third parties could delay clinical development

or marketing approval of our product candidates or commercialization of our product candidates, if approved, producing additional losses and depriving us of potential product revenue.

Our CMOs, CROs, clinical trial sites and other third parties may also have relationships with other entities, some of which may be our competitors, for whom they may also be conducting clinical trials or other therapeutic development activities that could harm our competitive position. In addition, these third parties are not our employees, and except for remedies available to us under our agreements with them, we cannot control whether or not they devote sufficient time and resources to our ongoing clinical trials and preclinical programs. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, if they need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical trial protocols, regulatory requirements or for other reasons, our clinical trials may need to be repeated, extended, delayed or terminated. In the event we need to repeat, extend, delay or terminate our clinical trials, we may not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates, and we will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates or we or they may be subject to regulatory enforcement actions. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed. To the extent we are unable to successfully identify and manage the performance of third-party service providers in the future, our business may be materially and adversely affected.

If any of our relationships with these third parties terminate, we may not be able to enter into alternative arrangements or do so on commercially reasonable terms. Switching or adding additional contractors involves additional cost and time and requires management time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, delays could occur, which could compromise our ability to meet our desired development timelines. In addition, if an agreement with any of our collaborators terminates, our access to technology and intellectual property licensed to us by that collaborator may be restricted or terminate entirely, which may delay our continued development of our product candidates utilizing the collaborator's technology or intellectual property or require us to stop development of those product candidates completely.

As of June 1, 2021, we have a sponsored Phase 1 SAD trial of VTX958 engaged in enrollment of healthy subjects. Our relative lack of experience conducting clinical trials may contribute to our planned clinical trials not beginning or completing on time, if at all. Large-scale clinical trials will require significant additional resources and reliance on CROs, clinical investigators or consultants. Consequently, our reliance on outside parties may introduce delays beyond our control. Our CROs and other third parties must communicate and coordinate with one another in order for our trials to be successful. Additionally, our CROs and other third parties may also have relationships with other commercial entities, some of which may compete with us. If our CROs or other third parties conducting our clinical trials do not perform their contractual duties or regulatory obligations, experience work stoppages, do not meet expected deadlines, terminate their agreements with us or need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical trial protocols, GCP or other regulatory requirements or for any other reason, we may need to conduct additional clinical trials or enter into new arrangements with alternative CROs, clinical investigators or other third parties. We may be unable to enter into arrangements with alternative CROs on commercially reasonable terms, or at all.

We and the third parties upon which we rely are required to comply with GCP. GCP are regulations and guidelines enforced by regulatory authorities around the world, through periodic inspections, for products in clinical development. If we or these third parties fail to comply with applicable GCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and have to be repeated, and our submission of marketing applications may be delayed or the regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We are subject to the risk that, upon inspection, a regulatory authority will determine that any of our clinical trials fails to comply or failed to comply with applicable GCP regulations. In addition, our clinical trials must be conducted with material produced under GMP regulations, which are enforced by regulatory authorities. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be significantly impacted if our CROs, clinical investigators or other third parties violate federal or state healthcare fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

We also anticipate that part of our strategy for pursuing the wide range of indications potentially addressed by our product candidates may involve further investigator-initiated clinical trials. While these trials generally provide us with valuable clinical data that can inform our future development strategy in a cost-efficient manner, we generally have less control over not only the conduct but also the design of these clinical trials. Third-party investigators may design clinical trials involving our product candidates with clinical endpoints that are more difficult to achieve or in other ways that increase the risk of negative clinical trial results compared to clinical trials we may design on our own. Negative results in investigator-initiated clinical trials, regardless of how the clinical trial was designed or conducted, could have a material adverse effect on our prospects and the perception of our product candidates.

Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA. The FDA may conclude that a financial relationship between us and/or a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA and may ultimately lead to the denial of regulatory approval of one or more of our product candidates.

We may be required to conduct additional clinical trials or modify current or future clinical trials.

Clinical testing is expensive, time consuming and subject to uncertainty. We cannot guarantee that any current or future clinical studies will be conducted as planned or completed on schedule, if at all, or that any of our product candidates will receive regulatory approval. We plan to initiate trials in multiple indications, such as psoriasis, UC and Crohn's disease, among others. Even as these trials progress, issues may arise that could require us to suspend or terminate such clinical trials or could cause the results of one cohort to differ from a prior cohort. For example, we may experience slower than anticipated enrollment in our clinical trials, which may consequently delay our NDA filing timelines or permit competitors to obtain approvals that may alter our NDA filing strategy. A failure of one or more clinical trials can occur at any stage of testing, and our future clinical trials may not be successful. In addition, even if such clinical trials are successfully completed, we cannot guarantee that the FDA or foreign regulatory authorities will interpret the results as we do, and more trials could be required before we submit our product candidates for approval. To the extent that the results of the clinical trials are not satisfactory to the FDA or foreign regulatory authorities for support of a marketing application, we may be required to expend significant resources, which may not be available to us, to conduct additional clinical trials in support of potential approval of our product candidates.

Events that may prevent successful or timely initiation or completion of clinical development include:

- regulators or Institutional Review Boards, or IRBs may not authorize us or our investigators to commence a clinical trial, conduct a clinical trial at a prospective trial site, or amend trial protocols, or regulators or IRBs may require that we modify or amend our clinical trial protocols;
- delays in reaching a consensus or inability to obtain agreement with regulatory agencies on study design or eligibility criteria for patient enrollment;
- the FDA or comparable foreign regulatory authorities may disagree with our intended indications, study design or our interpretation of data from preclinical studies and clinical trials or find that a product candidate's benefits do not outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may not accept data from studies with clinical trial sites in foreign countries (e.g., Australia, Russia, Poland, Ukraine, Germany, Belgium, Georgia, Hungary, Israel, Belarus and Italy);
- the FDA may not allow us to use the clinical trial data from a research institution to support an IND if we cannot demonstrate the comparability of our product candidates with the product candidate used by the relevant research institution in its clinical studies;
- delays in or failure to reach an agreement on acceptable terms with prospective CROs and clinical study sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical study sites;
- imposition of a temporary or permanent clinical hold, suspensions or terminations by regulatory agencies, IRBs, or us for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks, undesirable side effects or other unexpected characteristics of the product candidate, or due to findings of undesirable effects caused by a biologically or mechanistically similar therapeutic or therapeutic candidate;

- delays in adding new investigators or clinical trial sites, or withdrawal of clinical trial sites from a study;
- failure by our CROs, clinical trial sites or patients, or other third parties, or us to adhere to clinical study requirements, including regulatory, contractual or protocol requirements;
- failure to perform in accordance with the GCP requirements, or applicable regulatory guidelines in other countries;
- occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols to regulatory authorities and IRBs, and which may cause delays in our development programs, or changes to regulatory review times;
- there may be regulatory questions or disagreements regarding interpretations of data and results, or new information may emerge regarding our product candidates;
- changes in the standard of care on which a clinical development plan was based, which may require new or additional trials;
- the cost of clinical studies of our product candidates being greater than we anticipate, or we may have insufficient funds for a clinical trial or to pay the substantial user fees required by the FDA upon the filing of an NDA;
- clinical trials of our product candidates producing negative or inconclusive results may fail to provide sufficient data and information to support product approval, or our clinical trials may fail to reach the necessary level of statistical or clinical significance, which may result in our deciding, or regulators requiring us, to conduct additional clinical trials, or preclinical studies, or abandon product development programs;
- interruption of, or delays in receiving, supplies of our product candidates or other drugs or components of our therapies due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems;
- early results from our clinical trials of our product candidates may be negatively affected by changes in efficacy measures, such as overall response rate and duration of response, as more patients are enrolled in our clinical trials or as new cohorts of our clinical trials are tested, and overall response rate and duration of response may be negatively affected by the inclusion of unconfirmed responses in preliminary results that we report if such responses are not later confirmed;
- we may not be able to demonstrate that a product candidate provides an advantage over current standards of care or current or future competitive therapies in development;
- there may be changes to the therapeutics or their regulatory status, which we are administering in combination with our product candidates;
- the FDA or comparable foreign regulatory authorities may fail to approve or subsequently find fault with the manufacturing processes or our manufacturing facilities for clinical and future commercial supplies;
- the FDA or comparable regulatory authorities may take longer than we anticipate making a decision on our product candidates;
- transfer of our manufacturing processes to our CMOs or other larger-scale facilities operated by a CMO or by us and delays or failure by our CMOs or us to make any necessary changes to such manufacturing process;
- our use of different manufacturing processes within our clinical trials, and any effects that may result from the use of different processes on the clinical data that we have reported and will report in the future;
- delays in manufacturing, testing, releasing, validating or importing/exporting sufficient stable quantities of our product candidates for use in clinical trials or the inability to do any of the foregoing, including as a result of any quality issues associated with the CMO; and
- delays and additional costs associated with business disruptions, new regulatory requirements, social distancing and other restrictions imposed by governmental or regulatory agencies and clinical trial sites due to the COVID-19 pandemic, which may include enrollment delays or failures to follow trial protocols.

We also may conduct clinical and preclinical research in collaboration with other academic, pharmaceutical and biotechnology entities in which we combine our technologies with those of our collaborators. Such collaborations may be subject to additional delays because of the management of the trials, contract negotiations, the need to obtain agreement from multiple parties and the necessity of obtaining additional

approvals for therapeutics used in the combination trials. These combination therapies will require additional testing and clinical trials will require additional FDA regulatory approval and will increase our future cost of expenses.

Any inability to successfully complete preclinical and clinical development could result in additional costs to us or impair our ability to generate revenue. In addition, if we make manufacturing changes to our product candidates, we may be required to, or we may elect to, conduct additional studies to bridge our modified product candidates to earlier versions. These changes may require FDA approval or notification and may not have their desired effect. The FDA may also not accept data from prior versions of the product to support an application, delaying our clinical trials or programs or necessitating additional clinical trials or preclinical studies. We may find that this change has unintended consequences that necessitates additional development and manufacturing work, additional clinical trials and preclinical studies, or that results in refusal to file or non-approval of an NDA.

Clinical trial delays could shorten any periods during which our product candidates have patent protection and may allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize our product candidates and may harm our business and results of operations.

Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. The number and types of preclinical studies and clinical trials that will be required for regulatory approval also vary depending on the product candidate, the disease or condition that the product candidate is designed to address and the regulations applicable to any particular product candidate. Approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. It is possible that any product candidates we may seek to develop in the future will never obtain the appropriate regulatory approvals necessary for us or any future collaborators to commence product sales. Any delay in completing development or obtaining, or failing to obtain, required approvals could also materially adversely affect our ability or that of any of our collaborators to generate revenue from any such product candidate, which likely would result in significant harm to our financial position and adversely impact our stock price.

Our product candidates may cause undesirable side effects or have other properties that could halt their clinical development, prevent their regulatory approval, limit their commercial potential or result in significant negative consequences, which could harm our business, financial condition, results of operations, and prospects significantly.

Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects, adverse events or unexpected characteristics. Undesirable side effects caused by our product candidates could cause us, IRBs, Drug Safety Monitoring Boards, or DSMBs, or the FDA or comparable foreign regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authorities. Even if we were to receive product approval, such approval could be contingent on inclusion of unfavorable information in our product labeling, such as limitations on the indicated uses for which the products may be marketed or distributed, a label with significant safety warnings, including boxed warnings, contraindications, and precautions, a label without statements necessary or desirable for successful commercialization, or requirements for costly post marketing testing and surveillance, or other requirements, including a Risk Evaluation and Mitigation Strategy, or REMS, to monitor the safety or efficacy of the products, and in turn prevent us from commercializing and generating revenues from the sale of our current or future product candidates.

If unacceptable toxicities or side effects arise in the development of our product candidates, IRBs, DSMBs or the FDA or comparable foreign regulatory authorities could order us to cease clinical trials, order our clinical trials to be placed on clinical hold, or deny approval of our product candidates for any or all targeted indications. The FDA or comparable foreign regulatory authorities may also require additional data, clinical, or pre-clinical studies should unacceptable toxicities arise. We may need to abandon development or limit development of that product candidate to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk/benefit perspective. Toxicities associated with our clinical trials and products may also negatively impact our ability to conduct clinical trials in larger patient populations, such as in patients that have not yet been treated with other therapies or have not yet progressed on other therapies.

Treatment-emergent adverse events could also affect patient recruitment or the ability of enrolled subjects to complete our clinical trials or could result in potential product liability claims. Potential side effects associated with our product candidates may not be appropriately recognized or managed by the treating medical staff, as toxicities resulting from our product candidates may not be normally encountered in the general patient population and by medical personnel. Any of these occurrences could harm our business, financial condition, results of operations, and prospects significantly.

The manufacturing of our product candidates is complex, and we may encounter difficulties in production, particularly with respect to process development, quality control, and scaling-up of our manufacturing capabilities. If we or our third-party manufacturers encounter such difficulties, our ability to provide supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or stopped, or we may be unable to achieve and maintain a commercially viable cost structure.

Currently, our product candidates are manufactured using processes developed by our third-party CMOs that we may not intend to use for more advanced clinical trials or commercialization. We may ultimately be unable to reduce the cost of goods for our product candidates to levels that will allow for an attractive return on investment if and when those product candidates are commercialized.

Our product candidates may compete with other products and product candidates for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that are both capable of manufacturing for us and willing to do so. If our CMOs should cease manufacturing for us, we would experience delays in obtaining sufficient quantities of our product candidates for clinical trials and, if approved, commercial supply. Further, our CMOs may breach, terminate or not renew these agreements. If we were to need to find alternative manufacturing facilities it would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. The commercial terms of any new arrangement could be less favorable than our existing arrangements and the expenses relating to the transfer of necessary technology and processes could be significant.

Reliance on third-party manufacturers entails exposure to risks to which we would not be subject if we manufactured the product candidate ourselves, including:

- inability to negotiate manufacturing and quality agreements with third parties under commercially reasonable terms;
- reduced day-to-day control over the manufacturing process for our product candidates as a result of using third-party manufacturers for all aspects of manufacturing activities;
- reduced control over the protection of our trade secrets, know-how and other proprietary information from misappropriation or inadvertent disclosure or from being used in such a way as to expose us to potential litigation;
- termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that may be costly or damaging to us or result in delays in the development or commercialization of our product candidates; and
- disruptions to the operations of our third-party manufacturers or suppliers caused by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier.

Any problems or delays we or our CMOs experience in preparing for commercial scale manufacturing of a product candidate may result in a delay in the FDA approval of the product candidate or may impair our ability to manufacture commercial quantities or such quantities at an acceptable cost, which could result in the delay, prevention or impairment of clinical development and commercialization of our product candidates and could adversely affect our business. Furthermore, if our product candidates are approved and we or our commercial manufacturers fail to deliver the required commercial quantities of our product candidates on a timely basis and at reasonable costs, we would likely be unable to meet demand for our products and we would lose potential revenues, which would adversely affect our business, financial condition, results of operations, and prospects.

In addition, the manufacturing process and facilities for any product candidates that we may develop is subject to FDA and foreign regulatory authority approval processes, and we or our CMOs will need to meet all applicable FDA and foreign regulatory authority requirements, including cGMP, on an ongoing basis. The cGMP requirements include quality control, quality assurance and the maintenance of records and documentation. The FDA and other regulatory authorities enforce these requirements through facility inspections. Manufacturing facilities must submit to pre-approval inspections by the FDA that will be conducted

after we submit our marketing applications, including our NDAs, to the FDA. Manufacturers are also subject to continuing FDA and other regulatory authority inspections following marketing approval. Further, we, in cooperation with our CMOs, must supply all necessary chemistry, manufacturing and quality control documentation in support of an NDA on a timely basis. There is no guarantee that we or our CMOs will be able to successfully pass all aspects of a pre-approval inspection by the FDA or other foreign regulatory authorities.

Our CMOs' manufacturing facilities may be unable to comply with our specifications, cGMP, or with other FDA, state, and foreign regulatory requirements. Poor control of production processes can lead to the introduction of adventitious agents or other contaminants, or to inadvertent changes in the properties or stability of product candidate that may not be detectable in final product testing. If we or our CMOs are unable to reliably produce products to specifications acceptable to the FDA or other regulatory authorities, or in accordance with the strict regulatory requirements, we may not obtain or maintain the approvals we need to commercialize such products. Even if we obtain regulatory approval for any of our product candidates, there is no assurance that either we or our CMOs will be able to manufacture the approved product to specifications acceptable to the FDA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product, or to meet potential future demand. Deviations from manufacturing requirements may further require remedial measures that may be costly and/or time-consuming for us or a third party to implement and may include the temporary or permanent suspension of a clinical trial or, if approved, commercial sales or the temporary or permanent closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business, financial condition, results of operations, and prospects.

Even to the extent we use and continue to use CMOs, we are ultimately responsible for the manufacture of our products and product candidates. A failure to comply with these requirements may result in regulatory enforcement actions against our manufacturers or us, including fines and civil and criminal penalties, which could result in imprisonment, suspension or restrictions of production, injunctions, delay or denial of product approval or supplements to approved products, clinical holds or termination of clinical trials, warning or untitled letters, regulatory authority communications warning the public about safety issues, refusal to permit the import or export of the products, product seizure, detention, or recall, operating restrictions, suits under the civil False Claims Act, corporate integrity agreements, consent decrees, or withdrawal of product approval.

Any of these challenges could delay completion of clinical trials, require bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidate, impair commercialization efforts, increase our cost of goods, and have an adverse effect on our business, financial condition, results of operations and prospects.

Small molecule therapeutics rely on the availability of reagents, intermediates, specialized equipment and other specialty materials, which may not be available to us on acceptable terms or at all. For some of these reagents, intermediates, specialized equipment and other specialty materials, we rely or may rely on sole source vendors or a limited number of vendors, which could impair our ability to manufacture and supply our product candidates.

Manufacturing our product candidates requires many reagents, which are substances used in our manufacturing processes to bring about chemical reactions, intermediates, specialized equipment and other specialty materials, some of which are manufactured or supplied by small companies with limited resources and experience to support commercial production. We currently depend on a limited number of vendors for certain intermediates, specialized equipment and other specialty materials used in the manufacture of our product candidates. Some of these suppliers may not have the capacity to support clinical trials and commercial products manufactured under cGMP or may otherwise be ill-equipped to support our needs. Accordingly, we may experience delays in receiving key intermediates, materials and equipment to support clinical or commercial manufacturing.

For some of these reagents, intermediates, equipment and materials, we currently rely and may in the future rely on sole source vendors or a limited number of vendors. An inability to continue to source product from any of these suppliers, which could be due to a number of issues, including regulatory actions or requirements affecting the supplier, adverse financial or other strategic developments experienced by a supplier, labor disputes or shortages, unexpected demands or quality issues, could adversely affect our ability to satisfy demand for our product candidates. If our product candidates are approved, such inability to source product from our suppliers could adversely and materially affect our product sales and operating results or our ability to conduct clinical trials, either of which could significantly harm our business.

As we continue to develop and scale our manufacturing process, we expect that we will need to obtain rights to and supplies of certain reagents, intermediates, equipment and materials to be used as part of that process. We may not be able to obtain rights to such reagents, intermediates, equipment and materials on commercially reasonable terms, or at all, and if we are unable to alter our process in a commercially viable manner to avoid the use of such reagents, intermediates, equipment or materials or find a suitable substitute, it would have a material adverse effect on our business. Even if we are able to alter our process so as to use other reagents, intermediates, equipment or materials, such a change may lead to a delay in our clinical development and, if approved, commercialization plans. If such a change occurs for a product candidate that is already in clinical testing, the change may require us to perform comparability studies and to collect additional data from patients prior to undertaking more advanced clinical trials, which may cause delays in our clinical development and commercialization plans.

Changes in the manufacturing process or formulation may result in additional costs or delay.

As product candidates progress through preclinical studies and clinical trials to marketing approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize yield and manufacturing batch size, minimize costs and achieve consistent quality and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commercialize our product candidates, if approved, and generate revenue. If we or our CMOs are not able to successfully manufacture our product candidates in sufficient quality and quantity, clinical development and timelines for our product candidates and subsequent approval could be adversely impacted.

We will be unable to commercialize our products if our clinical trials are not successful.

Our research and development programs are at an early stage. We must demonstrate our products' safety and efficacy in humans through extensive clinical testing. We may experience numerous unforeseen events during, or as a result of, the clinical testing process that could delay or prevent commercialization of our products, including but not limited to the following:

- safety and efficacy results in various human clinical trials reported in scientific and medical literature may not be indicative of results we obtain in our clinical trials;
- after reviewing test results, we or our collaborators may abandon projects that we might previously have believed to be promising;
- we, our collaborators or regulators may suspend or terminate clinical trials if the participating subjects or patients are being exposed to unacceptable health risks;
- the standard of care may change as the result of new technology or therapies in our target clinical indications, precluding regulatory approval or limited commercial use if approved;
- the effects our product candidates have may not be the desired effects or may include undesirable side effects or other characteristics that preclude regulatory approval or limit their commercial use if approved;
- manufacturers may not meet the necessary standards for the production of the product candidates or may not be able to supply the product candidates in a sufficient quantity; and
- regulatory authorities may find that our clinical trial design or conduct does not meet the applicable approval requirements.

Clinical testing is very expensive, can take many years and the outcome is uncertain. The data collected from our clinical trials may not be sufficient to support approval by the FDA of our product candidates for the treatment of inflammatory diseases and autoimmune disorders. The clinical trials for our product candidates under development may not be completed on schedule and the FDA may not ultimately approve any of our product candidates for commercial sale. If we fail to adequately demonstrate the safety and efficacy of any product candidate under development, we may not receive regulatory approval for such product candidate, which would prevent us from generating revenues or achieving profitability.

We may use our limited financial and human resources to pursue a particular type of treatment, or treatment for a particular type of disease, and fail to capitalize on programs or treatments of other types of diseases that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and human resources, we must choose to pursue and fund the development of specific types of treatment, or treatment for a specific type of disease, and may forego or delay pursuit of opportunities with other programs, investigational medicines, or treatment for other types of diseases, which could later prove to have greater commercial potential. Moreover, given the rapidly evolving competitive landscape and the time it takes to advance a product through clinical development, an incorrect decision to pursue a particular type of treatment or disease may have a material adverse effect on our results of operation and negatively impact our future clinical strategies. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs for investigational medicines or clinical trials may not yield any commercially viable products. If we do not accurately evaluate and anticipate the commercial potential or target market for a particular type of treatment or disease, we may choose to spend our limited resources on a particular treatment, or treatment for a particular type of disease, and then later learn that another type of treatment or disease that we previously decided not to pursue would have been more advantageous. We may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights. Any such event could have a material adverse effect on our business, financial condition, results of operations, and prospects.

We may develop product candidates in combination with other therapies, which exposes us to additional risks and could result in our products, even if approved, being removed from the market or being less successful commercially.

We may develop product candidates in combination with one or more other therapies. Even if any product candidate we develop were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA or comparable foreign regulatory authorities could revoke approval of the therapy used in combination with our product or that safety, efficacy, manufacturing or supply issues could arise with any of those existing therapies. If the therapies we use in combination with our product candidates are replaced as the standard of care for the indications we choose for any of our product candidates, the FDA or comparable foreign regulatory authorities may require us to conduct additional clinical trials. The occurrence of any of these risks could result in our own products, even if approved, being removed from the market or being less successful commercially.

We also may choose to evaluate product candidates in combination with one or more therapies that have not yet been approved for marketing by the FDA or comparable foreign regulatory authorities. We will not be able to market and sell any product candidate we develop in combination with an unapproved therapy for a combination indication if that unapproved therapy does not ultimately obtain marketing approval either alone or in combination with our product. In addition, unapproved therapies face the same risks described with respect to our product candidates currently in development and clinical trials, including the potential for serious adverse effects, delay in their clinical trials and lack of FDA approval. If the FDA or comparable foreign regulatory authorities do not approve these other drugs or revoke their approval of, or if safety, efficacy, quality, manufacturing or supply issues arise with, the drugs we choose to evaluate in combination with our product candidate we develop, we may be unable to obtain approval of or market such combination therapy.

Even if this offering is successful, we will need additional financing to fund our operations and complete the development and, if approved, commercialization of our various product candidates. If we are unable to obtain such financing on acceptable terms, or at all, we would be unable to complete the development and commercialization of our product candidates. Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our product candidates.

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is a very time-consuming, expensive and uncertain process that takes years to complete. Our operations have consumed substantial amounts of cash since inception. As of December 31, 2020, we had an accumulated deficit of $32.5 million. In addition, our research and development and our operating costs have also been substantial and are expected to increase.

As of June 30, 2021, we had cash and cash equivalents of $102.8 million. After the completion of this offering, we believe that the net proceeds from this offering, together with our existing cash and cash equivalents will be sufficient to fund our operations for at least the next months from the date of this prospectus. However, in order to complete the development of our current product candidates, and in order to implement our business plan, we anticipate that we will have to spend more than the funds currently available to us. Furthermore, changing circumstances may cause us to increase our spending significantly faster than we currently anticipate, and we may require additional capital for the further development and, if approved, commercialization of our product candidates and may need to raise additional funds sooner if we choose to expand more rapidly than we presently anticipate. Moreover, our fixed expenses, such as rent and other contractual commitments, are substantial and are expected to increase in the future.

We will need to obtain additional financing to fund our future operations, including completing the development and, if approved, commercialization of our product candidates. Our future capital requirements will depend on many factors, including, but not limited to:

- progress, timing, scope and costs of our clinical trials, including the ability to timely initiate clinical sites, enroll subjects and manufacture product candidates for the treatment of patients in our ongoing, planned and potential future clinical trials;
- the continued effect of the COVID-19 pandemic on our business;
- time and cost necessary to obtain regulatory approvals that may be required by regulatory authorities to execute clinical trials;
- our ability to successfully commercialize any product candidates, if approved;
- our ability to have clinical and commercial product successfully manufactured consistent with FDA and European Medicines Agency, or EMA, regulations;
- our ability to achieve sufficient market acceptance and adequate market share and revenue for any approved products;
- amount of sales and other revenues from product candidates that we may commercialize, if any, including the selling prices for such potential products and the availability of adequate third-party coverage and reimbursement for patients;
- sales and marketing costs associated with commercializing any product candidates, if approved, including the cost and timing of building our marketing and sales capabilities;
- cost of potentially building, staffing and validating our own manufacturing facility in the United States;
- terms and timing of any potential future collaborations, milestone, royalty, licensing or other arrangements that we may establish;
- cash requirements of any future acquisitions or the development of other product candidates;
- costs of operating as a public company;
- time and cost necessary to respond to technological, regulatory, political and market developments;
- costs of filing, prosecuting, maintaining, defending and enforcing any patent claims and other intellectual property rights; and
- costs associated with any strategic collaborations, licensing agreements or other arrangements that we may establish.

Unless and until we can generate a sufficient amount of revenue, we will finance future cash needs through public or private equity offerings, license agreements, debt financings, collaborations, strategic alliances and marketing or distribution arrangements. Additional funds may not be available when we need them on terms that are acceptable to us, or at all. We have no committed source of additional capital and if we are unable to raise additional capital in sufficient amounts, on terms acceptable to us or at all, we may be required to delay or reduce the scope of or eliminate one or more of our research or development programs or, if approved, our commercialization efforts. In addition, we may seek to access the public or private capital markets whenever conditions are favorable, even if we do not have an immediate need for additional capital at that time.

To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. The incurrence of additional indebtedness would result in increased fixed payment obligations and could involve certain restrictive covenants, such as limitations on our ability to incur additional debt, to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or product candidates, or grant licenses on terms unfavorable to us.

The use of our net operating loss carryforwards may be limited.

Our net operating loss carryforwards may expire and not be used. As of December 31, 2020, we had U.S. federal net operating loss carryforwards of approximately $11.0 million. Our U.S. federal net operating loss carryforwards arising in taxable years beginning after December 31, 2017, are not subject to expiration under the Internal Revenue Code of 1986, as amended, or the Code. For taxable years beginning after December 31, 2020, however, the deductibility of U.S. federal net operating losses arising in taxable years beginning after December 31, 2017, is limited to 80% of our current year taxable income. Additionally, our ability to use any net operating loss carryforwards to offset taxable income in the future will also be limited under Section 382 of the Code, if we undergo an "ownership change" (generally defined as a cumulative change in ownership by "5-percent shareholders" of more than 50% within a rolling three-year period).

We may have experienced ownership changes in the past and, although we do not expect to experience an ownership change in connection with our listing on the Nasdaq Global Market, any such ownership change could result in increased future tax liability. In addition, since we will need to raise substantial additional funding to finance our operations, we may undergo ownership changes in the future. In addition, we may experience ownership changes in the future as a result of subsequent shifts in our stock ownership. In addition, since we will need to raise substantial additional funding to finance our operations, we may undergo ownership changes in the future. Any such annual limitation may significantly reduce the utilization of the net operating loss carryforwards before they expire. Depending on our future tax position, limitation of our ability to use net operating loss carryforwards in jurisdictions in which we are subject to income tax could have an adverse impact on our results of operations and financial condition.

There is also a risk that due to regulatory changes, such as suspensions on the use of net operating losses by certain jurisdictions, including in order to raise additional revenue to help counter the fiscal impact from the COVID-19 pandemic, possibly with retroactive effect, or other unforeseen reasons, our existing net operating losses could expire or otherwise be unavailable to offset future income tax liabilities. A temporary suspension of the use of certain net operating losses has been enacted in California, and other states may enact suspensions as well.

We may experience fluctuations in our tax obligations and effective tax rate, which could materially affect our results.

We are subject to income- and non-income-based taxes in the United States under federal, state, and local jurisdictions and in certain foreign jurisdictions in which we operate. Tax laws, regulations and administrative practices in various jurisdictions may be subject to significant change, with or without advance notice, due to economic, political and other conditions, and significant judgment is required in evaluating and estimating our provision and accruals for these taxes. Our effective tax rates could be affected by numerous factors, such as changes in tax, accounting and other laws, regulations, administrative practices, principles and interpretations, the mix and level of earnings in a given taxing jurisdiction or our ownership or capital structures.

Further, U.S. federal income tax legislation referred to as the Tax Cuts and Jobs Act, is highly complex, is subject to interpretation, and contains significant changes to U.S. tax law, including, but not limited to, a reduction in the corporate tax rate, significant additional limitations on the deductibility of interest, substantial revisions to the taxation of international operations, and limitations on the use of certain net operating losses. The presentation of our financial condition and results of operations is based upon our current interpretation of the provisions contained in the Tax Cuts and Jobs Act. The Treasury Department and the U.S. Internal Revenue Service, or IRS, have released and are expected to continue releasing regulations and interpretive guidance relating to the legislation contained in the Tax Cuts and Jobs Act. Any significant variance of our current interpretation of such legislation from any future regulations or interpretive guidance could result in a change to the presentation of our financial condition and results of operations and could materially and adversely affect our business, financial condition, and results of operations.

Furthermore, in the second quarter of 2021, the Biden administration proposed changes to the U.S. tax system, including an increase to the U.S. corporate tax rate. We are unable to predict which, if any, U.S. tax reform proposals will be enacted into law, and what effects any enacted legislation might have on our liability for U.S. corporate tax. However, it is possible that the enactment of changes in the U.S. corporate tax system could have a material adverse effect on our liability for U.S. corporate tax and our consolidated effective tax rate.

Our international operations subject us to potentially adverse tax consequences.

We generally conduct our international operations through subsidiaries and report our taxable income in various jurisdictions worldwide based upon our business operations in those jurisdictions. Our intercompany

relationships are subject to complex transfer pricing regulations administered by taxing authorities in various jurisdictions. The relevant taxing authorities may disagree with our determinations as to the value of assets sold or acquired or income and expenses attributable to specific jurisdictions. If such a disagreement were to occur, and our position were not sustained, we could be required to pay additional taxes, interest and penalties, which could result in one-time tax charges, higher effective tax rates, reduced cash flows, and lower overall profitability of our operations.

We are subject to extensive regulation, which can be costly, time consuming and can subject us to unanticipated delays. Even if we obtain regulatory approval for some of our products, those products may still face regulatory difficulties.

Our product candidates and manufacturing activities are subject to comprehensive regulation by the FDA in the United States and by comparable authorities in other countries. The process of obtaining FDA and other required regulatory approvals, including foreign approvals, is expensive and often takes many years and can vary substantially based upon the type, complexity and novelty of the products involved. In addition, regulatory agencies may lack experience with our product candidates, which may lengthen the regulatory review process, increase our development costs and delay or prevent their commercialization.

If we violate regulatory requirements at any stage, whether before or after marketing approval is obtained, we may face a number of regulatory consequences, including refusal to approve pending applications, license suspension or revocation, withdrawal of an approval, imposition of a clinical hold or termination of clinical trials, warning letters, untitled letters, modification of promotional materials or labeling, provision of corrective information, imposition of post-market requirements, including the need for additional testing, imposition of distribution or other restrictions under a REMS, product recalls, product seizures or detentions, refusal to allow imports or exports, total or partial suspension of production or distribution, FDA debarment, injunctions, fines, consent decrees, corporate integrity agreements, debarment from receiving government contracts, exclusion from participation in federal and state healthcare programs, restitution, disgorgement, or civil or criminal penalties, including fines and imprisonment, and adverse publicity, among other adverse consequences. Additionally, we may not be able to obtain the labeling claims necessary or desirable for the promotion of our products. We may also be required to undertake post-marketing trials. In addition, if we or others identify side effects after any of our products are on the market, or if manufacturing problems occur, regulatory approval may be withdrawn, and reformulation of our products may be required.

Our projections regarding the market opportunities for our product candidates may not be accurate, and the actual market for our products may be smaller than we estimate.

We do not have verifiable internal marketing data regarding the potential size of the commercial market for our product candidates, nor have we obtained current independent marketing surveys to verify the potential size of the commercial markets for our current product candidates or any future product candidates. Since our current product candidates and any future product candidates will represent novel approaches to treating various conditions, it may be difficult, in any event, to accurately estimate the potential revenues from these product candidates. Accordingly, we may spend significant capital trying to obtain approval for product candidates that have an uncertain commercial market. Our projections of both the number of people who have inflammatory diseases and autoimmune disorders we are targeting, as well as the subset of people with these diseases who are in a position to receive second- or third- line therapy, and who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations, or market research by third parties, and may prove to be incorrect. Further, new studies or approvals of new therapeutics may change the estimated incidence or prevalence of these diseases. The number of patients may turn out to be lower than expected. Additionally, the potentially addressable patient population for our product candidates may be limited or may not be amenable to treatment with our product candidates and may also be limited by the cost of our treatments and the reimbursement of those treatment costs by third-party payors. Even if we obtain significant market share for our product candidates, because the potential target populations may be small, we may never achieve profitability without obtaining regulatory approval for additional indications.

Because our current product candidates represent, and our other potential product candidates will represent, novel approaches to the treatment of disease, there are many uncertainties regarding the development, the market acceptance, third-party reimbursement coverage and the commercial potential of our product candidates.

There are many uncertainties related to development, marketing, reimbursement and the commercial potential for our product candidates. There can be no assurance as to the length of the trial period, the number of patients the FDA will require to be enrolled in the trials in order to establish the safety and efficacy of our

product candidates, or that the data generated in these clinical trials will be acceptable to the FDA to support marketing approval. The FDA may take longer than usual to come to a decision on any NDA that we submit and may ultimately determine that there is not enough data, information or experience with our product candidates to support an approval decision. The FDA may also require that we conduct additional post-marketing studies or implement risk management programs, such as REMS, until more experience with our product candidates is obtained. Finally, after increased usage, we may find that our product candidates do not have the intended effect, do not work with other combination therapies or have unanticipated side effects, potentially jeopardizing initial or continuing regulatory approval and commercial prospects.

There is no assurance that our product candidates will gain broad acceptance among doctors or patients or that governmental agencies or third-party medical insurers will be willing to provide reimbursement coverage for proposed product candidates. The market for any product candidates that we develop, if approved, will also depend on the cost of the product candidate. We do not yet have sufficient information to reliably estimate what it will cost to commercially manufacture our current product candidates, and the actual cost to manufacture these products could materially and adversely affect the commercial viability of these products. Unless we can reduce manufacturing costs to an acceptable amount, we may never be able to develop a commercially viable product. If we do not successfully develop and, if approved, commercialize products based upon our approach or find suitable and economical sources for materials used in the production of our products, we will not become profitable, which would materially and adversely affect the value of our common stock, our business, financial condition, results of operations, and prospects.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates, if approved.

We face an inherent risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk if we commercialize any products, if approved. For example, we may be sued if our product candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection laws. Large judgements have also been awarded in class action lawsuits based on therapeutics that had unanticipated side effects. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit or cease the commercialization of our product candidates, if approved. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our products, if approved;
- injury to our reputation or significant negative media attention;
- withdrawal of clinical trial participants or sites and potential termination of clinical trial sites or entire clinical programs;
- initiation of investigations by regulators, refusal to approve marketing applications or supplements, and withdrawal or limitation of product approvals;
- costs to defend litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- decrease in the price of our stock and overall value of our company;
- exhaustion of our available insurance coverage and our capital resources; or
- the inability to commercialize our product candidates.

Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we may develop, alone or with corporate collaborators. Our insurance policies may also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. While we have obtained clinical trial insurance for our clinical trials, we may have to pay amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

Public opinion and scrutiny of immunology treatments may impact public perception of our company and product candidates, or may adversely affect our ability to conduct our business and our business plans.

Public perception may be influenced by claims, such as claims that our product candidates are unsafe, unethical or immoral and, consequently, our approach may not gain the acceptance of the public or the medical community. Negative public reaction to new immunology treatments in general could result in greater government regulation and stricter labeling requirements of products to treat inflammatory diseases and autoimmune disorders, including any of our product candidates, if approved, and could cause a decrease in the demand for any product candidates we may develop. Adverse public attitudes may adversely impact our ability to enroll clinical trials. Moreover, our success will depend upon physicians specializing in the treatment of those diseases that our product candidates target prescribing, and their patients being willing to receive, treatments that involve the use of our product candidates in lieu of, or in addition to, existing treatments they are already familiar with and for which greater clinical data may be available. Adverse events in our clinical trials, even if not ultimately attributable to our product candidates, and the resulting publicity could result in increased governmental regulation, unfavorable public perception, potential regulatory delays in the testing or approval of our product candidates, stricter labeling requirements for those product candidates that are approved and a decrease in demand for any such product candidates. More restrictive government regulations or negative public opinion could have an adverse effect on our business, financial condition, results of operations and prospects, and may delay or impair the development and, if approved, commercialization of our product candidates or demand for any products we may develop.

We may be unable to establish effective marketing and sales capabilities or enter into agreements with third parties or related parties to market and sell our product candidates, if they are approved, and as a result, we may be unable to generate product revenues.

We currently do not have a commercial infrastructure for the marketing, sale and distribution of products. If approved, in order to commercialize our products, we must build our marketing, sales and distribution capabilities or make arrangements with third parties to perform these services, which will take time and require significant financial expenditures and we may not be successful in doing so. There are risks involved with establishing our own marketing and sales capabilities. For example, recruiting and training a sales force is expensive and time-consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have incurred these commercialization expenses prematurely or unnecessarily. These efforts may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel. Even if we are able to effectively establish a sales force and develop a marketing and sales infrastructure, our sales force and marketing teams may not be successful in commercializing our current or future product candidates. To the extent we rely on third parties to commercialize any products for which we obtain regulatory approval, we would have less control over their sales efforts and could be held liable if they failed to comply with applicable legal or regulatory requirements.

We have little to no prior experience in the marketing, sale and distribution of biopharmaceutical products, and there are significant risks involved in the building and managing of a commercial infrastructure. The establishment and development of commercial capabilities, including a comprehensive healthcare compliance program, to market any product candidates we may develop will be expensive and time consuming and could delay any product launch, and we may not be able to successfully develop this capability. We, or our collaborators, will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train, manage and retain medical affairs, marketing, sales and commercial support personnel. In the event we are unable to develop a commercial infrastructure, we may not be able to commercialize our current or future product candidates, which would limit our ability to generate product revenues. Factors that may inhibit our efforts to commercialize our current or future product candidates and generate product revenues include:

- if the COVID-19 pandemic continues or another pandemic occurs, it may negatively impact our ability to establish commercial operations, educate and interact with healthcare professionals, and successfully launch our product on a timely basis;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe our current or future product candidates;
- our inability to effectively oversee a geographically dispersed sales and marketing team;
- the costs and time associated with the initial and ongoing training of sales and marketing personnel on legal and regulatory compliance matters and monitoring their actions;
- an inability to secure adequate coverage and reimbursement by government and private health plans;

- intense competition in the clinical indications for which the products are approved and any restrictions on the scope of claims that we may make for the products;
- limitations or warnings, including distribution or use restrictions, contained in the products' approved labeling;
- any distribution and use restrictions imposed by the FDA or to which we agree as part of a mandatory REMS or voluntary risk management plan;
- liability for sales or marketing personnel who fail to comply with the applicable legal and regulatory requirements;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization or engaging a contract sales organization.

If our product candidates, if approved, do not achieve broad market acceptance, the revenues that we generate from their sales will be limited.

We have never commercialized a product candidate for any indication. Even if our product candidates are approved by the appropriate regulatory authorities for marketing and sale, they may not gain acceptance among physicians, patients, third-party payors and others in the medical community. If any product candidate for which we obtain regulatory approval does not gain an adequate level of market acceptance, we may not generate sufficient product revenues or become profitable.

Efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may not be successful. The degree of market acceptance of any of our product candidates will depend on a number of factors, some of which are beyond our control, including:

- the safety and efficacy of our product candidates;
- the prevalence and severity of adverse events associated with our product candidates;
- the clinical indications for which the products are approved and the approved claims that we may make for the products;
- limitations or warnings contained in the product's FDA-approved labeling, including potential limitations or warnings for such products that may be more restrictive than other competitive products;
- distribution and use restrictions imposed by the FDA with respect to such product candidates or to which we agree as part of a mandatory risk evaluation and mitigation strategy or voluntary risk management plan;
- changes in the standard of care for the targeted indications for such product candidates;
- the relative difficulty of administration of such product candidates;
- cost of treatment as compared to the clinical benefit in relation to alternative treatments or therapies;
- the availability of adequate coverage and reimbursement by third parties, such as insurance companies and other healthcare payors, and by government healthcare programs, including Medicare and Medicaid;
- the extent and strength of our marketing and distribution of such product candidates;
- the safety, efficacy and other potential advantages of, and availability of, alternative treatments already used or that may later be approved for any of our intended indications;
- the timing of market introduction of such product candidates, as well as competitive products;
- the reluctance of physicians to switch their patients' therapeutics;
- the reluctance of patients to switch from their existing therapeutics regardless of the safety and efficacy of newer therapeutics;
- our ability to offer such product candidates for sale at competitive prices;
- the extent and strength of our third-party manufacturer and supplier support;
- adverse publicity about our product or favorable publicity about competitive products; and
- potential product liability claims.

Our efforts to educate the medical community and third-party payors as to the benefits of our product candidates may require significant resources and may never be successful. Even if the medical community accepts that our product candidates are safe and effective for their approved indications, physicians and patients may not immediately be receptive to such product candidates and may be slow to adopt them as an

accepted treatment of the approved indications. If our current or future product candidates are approved, but do not achieve an adequate level of acceptance among physicians, patients, and third-party payors, we may not generate meaningful revenues from our product candidates and may never become profitable.

Our product candidates may face competition sooner than anticipated.

For small molecular product candidates, the Federal Food, Drug, and Cosmetic Act, or FDCA, provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to gain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application, or ANDA, or a 505(b)(2) NDA submitted by another company for a generic version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement. The FDCA also provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, new indications, dosages or strengths of an existing drug. As such, we may face competition from generic versions of our small molecule product candidates, which will negatively impact our long-term business prospects and marketing opportunities.

We will need to obtain FDA approval of any proposed branded product names, and any failure or delay associated with such approval may adversely affect our business.

Any name we intend to use for our product candidates in the United States will require approval from the FDA regardless of whether we have secured a formal trademark registration from the U.S. Patent and Trademark Office, or USPTO. The FDA typically conducts a review of proposed product names, including an evaluation of the potential for confusion with other product names. The FDA may also object to a product name if it believes the name inappropriately implies medical claims or contributes to an overstatement of efficacy. If the FDA objects to any of our proposed product names, we may be required to adopt alternative names for our product candidates. If we adopt alternative names, we will lose the benefit of any existing trademark applications for such product candidate and may be required to expend significant additional resources in an effort to identify a suitable product name that would qualify under applicable trademark laws, not infringe or otherwise violate the existing rights of third parties, and be acceptable to the FDA. We may be unable to build a successful brand identity for a new product name in a timely manner or at all, which would limit our ability to commercialize our product candidates.

We are dependent on information technology, systems, infrastructure and data. Our internal computer systems, or those used by our CROs, CMOs, clinical sites or other contractors or consultants, may fail or suffer security breaches, which could result in a material adverse effect, including without limitation, a material operational or service interruption, harm to our reputation, significant fines, penalties and liability, breach or triggering of data protection laws, or loss of customers or sales.

We are dependent upon information technology systems, infrastructure and data. In the ordinary course of our business, we directly or indirectly collect, use, generate, transfer, and disclose (collectively, “Process” or “Processing”) sensitive data, including intellectual property, confidential information, preclinical and clinical trial data, proprietary business information, personal data and personally identifiable health information of our clinical trial subjects and employees, in our data centers and on our networks, or on those of third-party service providers. The secure Processing of this information is critical to our operations. The multitude and complexity of our computer systems and those of our CROs, CMOs, clinical sites or other contractors or consultants make them inherently vulnerable to service interruption or destruction, malicious intrusion and random attack. Data privacy or security breaches by third-party service providers, employees, contractors or others may pose a risk that sensitive data, including our intellectual property, trade secrets or personal information of our employees, patients, or other business partners may be exposed to unauthorized persons or to the public.

Although we take measures designed to protect such information from unauthorized access or disclosure, our internal computer systems and those of our CROs, CMOs, clinical sites and other contractors and consultants are vulnerable to cyberattacks, computer viruses, bugs or worms, and other attacks by computer hackers, cracking, application security attacks, social engineering, supply chain attacks and vulnerabilities through our third-party service providers, denial-of-service attacks (such as credential stuffing), extortion, and intentional disruptions of service; computer and network vulnerabilities or the negligence and malfeasance of individuals with authorized access to our information, failure or damage from natural disasters, terrorism, war, fire and telecommunication and electrical failures. Ransomware attacks, including those from organized criminal threat

actors, nation-states and nation-state supported actors, are becoming increasingly prevalent and severe and can lead to significant interruptions, delays, or outages in our operations, loss of data (including sensitive customer information), loss of income, significant extra expenses to restore data or systems, reputational loss and the diversion of funds. To alleviate the financial, operational and reputational impact of a ransomware attack, it may be preferable to make extortion payments, but we may be unwilling or unable to do so (including, for example, if applicable laws or regulations prohibit such payments). Third parties may also attempt to fraudulently induce our employees, contractors, consultants, or third-party service providers into disclosing sensitive information such as user names, passwords, or other information or otherwise compromise the security of our computer systems, networks, and/or physical facilities in order to gain access to our data. Cyberattacks are increasing in their frequency, sophistication and intensity. The techniques used by cyber criminals change frequently, may not be recognized until launched and can originate from a wide variety of sources, including outside groups, such as external service providers, organized crime affiliates, terrorist organizations or hostile foreign governments or agencies. Additionally, due to the COVID-19 pandemic, some of our employees are temporarily working remotely, which may pose additional data security risks. While we have invested, and continue to invest, in the protection of our data and information technology infrastructure, there can be no assurance that our efforts, or the efforts of our partners, vendors, CROs, CMOs, clinical sites and other contractors and consultants will prevent service interruptions, or identify breaches in our or their systems, that could adversely affect our business and operations and/or result in the loss of critical or sensitive information, which could result in financial, legal, business or reputational harm to us. In addition, our liability insurance may not be sufficient in type or amount to cover us against claims related to security breaches, cyberattacks and other related breaches.

If any such event were to occur and cause interruptions in our operations, it could result in a disruption of our drug development programs. For example, the loss of clinical trial data from completed or ongoing clinical trials for a product candidate could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data, or may limit our ability to effectively execute a product recall, if required. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of personal, confidential or proprietary information, we could incur liability and the further development of any product candidates could be delayed. Any such event could also result in legal claims or proceedings, liability under laws that protect the privacy of personal information and significant regulatory penalties, and damage to our reputation and a loss of confidence in us and our ability to conduct clinical trials, which could delay the clinical development of our product candidates.

The COVID-19 pandemic has and could continue to adversely impact our business including our ongoing and planned clinical trials and preclinical research.

Outbreaks of epidemic, pandemic or contagious diseases, such as the COVID-19 pandemic, may significantly disrupt our operations and adversely affect our business, financial condition, results of operations and prospects. In March 2020, the World Health Organization declared the outbreak of the COVID-19 pandemic as the novel coronavirus continues to spread throughout the world. The spread of this COVID-19 pandemic has caused significant volatility and uncertainty in the U.S. and international markets and has resulted in increased risks to our operations.

Executive orders have been issued by state and local governments in California and elsewhere, and states of emergency have been declared at the state and local level in most jurisdictions throughout the United States. Quarantines, shelter-in-place and similar government orders, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could occur, related to the COVID-19 pandemic or other infectious diseases could impact our personnel or personnel at third-party manufacturing facilities in the United States and other countries, or the availability or cost of materials, which would disrupt our supply chain. We are monitoring a number of risks related to the COVID-19 pandemic, including the following:

- *Financial*: We anticipate that the pandemic could have an adverse financial impact in the short-term and potentially beyond. As a result of slower patient enrollment, we may not be able to complete our clinical trials as planned or in a timely manner. We expect to continue spending on research and development in the third quarter of 2021 and beyond, and we could also have unexpected expenses related to the COVID-19 pandemic. The short-term continued expenses, as well as the overall uncertainty and disruption caused by the COVID-19 pandemic, and any future pandemic, may cause a delay in our ability to commercialize a product and adversely impact our financial results.
- *Supply Chain*: An extended duration of the COVID-19 pandemic could result in significant disruptions in our supply chain and distribution. For example, quarantines, shelter-in-place and similar government orders, travel restrictions and health impacts of the COVID-19 pandemic, could impact the availability

or productivity of personnel at third-party laboratory supply manufacturers, distributors, freight carriers and other necessary components of our supply chain. In addition, there may be unfavorable changes in the availability or cost of raw materials, intermediates and other materials necessary for production, which may result in disruptions in our supply chain and adversely affect our ability to manufacture certain product candidates for clinical supply.

- *Clinical Trials*: The COVID-19 pandemic is likely to adversely affect certain of our clinical trials, including our ability to initiate and complete our clinical trials within the anticipated timelines. Due to site and participant availability during the COVID-19 pandemic, subject enrollment in our planned clinical trials has been slower than expected, at least in the short-term. Clinical trial sites have imposed restrictions on patient visits to limit risks of possible COVID-19 exposure, and we may experience issues with participant compliance with clinical trial protocols as a result of quarantines, travel restrictions and interruptions to healthcare services. The current pressures on medical systems and the prioritization of healthcare resources toward the COVID-19 pandemic have also resulted in interruptions in data collection and submissions for certain clinical trials and delayed starts for certain planned studies. As a result, our anticipated filing and marketing timelines may be adversely impacted.
- *Overall Economic and Capital Markets Environment*: The impact of the COVID-19 pandemic could result in a prolonged recession or depression in the United Stated or globally that could harm the banking system, limit demand for all products and services and cause other seen and unforeseen events and circumstances, all of which could negatively impact us. The continued spread of COVID-19 has led to and could continue to lead to severe disruption and volatility in the U.S. and global capital markets, which could result in a decline in our stock price, increase our cost of capital and adversely affect our ability to access the capital markets in the future. In addition, trading prices on the public stock market have been highly volatile as a result of the COVID-19 pandemic.
- *Regulatory Reviews*: The operations of the FDA or other regulatory agencies may be adversely affected. In response to the COVID-19 pandemic, federal, state and local governments are issuing new rules, regulations, orders and advisories on a regular basis. These government actions can impact us, our members and our suppliers. There is also the possibility that we may experience delays with obtaining approvals for our Investigational New Drug, or IND, applications and/or NDAs.

Our failure to comply with state, national and/or international data protection laws and regulations could lead to government enforcement actions and significant penalties against us, and adversely impact our operating results.

There are numerous laws and legislative and regulatory initiatives at the federal and state levels addressing privacy and security concerns, and some state privacy laws apply more broadly than the Health Insurance Portability and Accountability Act, or HIPAA, and associated regulations. For example, California recently enacted legislation—the California Consumer Privacy Act, or CCPA—which went into effect on January 1, 2020. The CCPA, among other things, creates new data privacy and security obligations for covered companies and provides new privacy rights to California consumers, including the right to opt out of certain disclosures of their information. The CCPA also provides for civil penalties as well as a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach. Although the law includes limited exceptions, including for certain information collected as part of clinical trials as specified in the law, it may regulate or impact our Processing of personal information depending on the context. Further, California voters recently approved the California Privacy Rights Act of 2020, or CPRA, that goes into effect on January 1, 2023. It is expected that the CPRA would, among other things, give California residents the ability to limit the use of their sensitive information, provide for penalties for CPRA violations concerning California residents under the age of 16, and establish a new California Privacy Protection Agency to implement and enforce the law.

There are also various laws and regulations in other jurisdictions relating to privacy and security. For example, the European Union, or EU, member states, the United Kingdom and other foreign jurisdictions, including Switzerland, have adopted data protection laws and regulations which impose significant compliance obligations on us. Moreover, the EU Data Protection Directive, which formerly governed the collection, Processing and other use of personal health or other data in the EU, was replaced with the EU General Data Protection Regulation, or the GDPR, in May 2018. The GDPR, which is wide-ranging in scope and applies extraterritorially, imposes several requirements relating to the consent of the individuals to whom the personal data relates, the information provided to such individuals, the security and confidentiality of the personal data, data breach notification, the adoption of appropriate privacy governance, including policies, procedures, training and audits, and the use of third-party processors in connection with the Processing of personal data. The GDPR also imposes strict rules on the transfer of personal data out of the EU, including to the U.S. In July

2020, in its Schrems II ruling, the Court of Justice of the EU invalidated the EU-U.S. Privacy Shield data transfer mechanism, limiting how organizations could lawfully transfer personal data from the EEA to the U.S. Other data transfer mechanisms such as the Standard Contractual Clauses approved by the European Commission have faced challenges in European courts (including being called into question in Schrems II), may require additional risk analysis and supplemental measures to be used, and may be challenged, suspended or invalidated. In addition, the European Commission recently provided updates to the Standard Contractual Clauses. Such developments may cause us to have to make further expenditures on local infrastructure, limit our ability to Process personal data, change internal business processes or otherwise affect or restrict sales and operation. Notably, the GDPR provides an enforcement authority and imposes large penalties for noncompliance, including the potential for fines of up to €20 million or 4% of the annual global revenues of the noncompliant entity, whichever is greater.

The United Kingdom implemented the Data Protection Act, effective May 2018 and statutorily amended in 2019, that contains provisions, including its own derogations, for how the GDPR is applied in the United Kingdom. These developments could increase the risk of non-compliance and the costs of providing our products and services in a compliant manner. From the beginning of 2021 (when the transitional period following Brexit expired), we have to continue to comply with the GDPR and also the Data Protection Act. We may incur substantial expense in complying with any new obligations, and we may be required to make significant changes in our business operations, all of which may adversely affect our revenues and our business overall.

Complying with these numerous, complex and often changing regulations is expensive and difficult, and failure to comply with any privacy laws or data security laws or any security incident or breach involving the misappropriation, loss or other unauthorized Processing, use or disclosure of sensitive or confidential patient, consumer or other personal information, whether by us, one of our CROs or business associates or another third party, could adversely affect our business, financial condition and results of operations, including but not limited to: investigation costs; material fines and penalties; compensatory, special, punitive and statutory damages; litigation; consent orders regarding our privacy and security practices; requirements that we provide notices, credit monitoring services and/or credit restoration services or other relevant services to impacted individuals; adverse actions against our licenses to do business; reputational damage; and injunctive relief. The recent implementation of the CCPA and GDPR has increased our responsibility and liability in relation to personal data that we Process, including in clinical trials, and we may in the future be required to put in place additional mechanisms to ensure compliance with the CCPA, GDPR and other applicable laws and regulations, which could divert management's attention and increase our cost of doing business. In addition, new regulation or legislative actions regarding data privacy and security (together with applicable industry standards) may increase our costs of doing business. In this regard, we expect that there will continue to be new proposed laws, regulations and industry standards relating to privacy and data protection in the United States, the EU and other jurisdictions, and we cannot determine the impact such future laws, regulations and standards may have on our business.

We cannot assure you that our CROs or other third-party service providers with access to our or our customers', suppliers', trial patients' and employees' personally identifiable and other sensitive or confidential information in relation to which we are responsible will not breach contractual obligations imposed by us, or that they will not experience data security breaches, which could have a corresponding effect on our business, including putting us in breach of our obligations under privacy laws and regulations and/or which could in turn adversely affect our business, results of operations and financial condition. We cannot assure you that our contractual measures and our own privacy and security-related safeguards will protect us from the risks associated with the third-party Processing of such information. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition to our legal obligations, our contractual obligations relating to privacy, data protection and data security have become increasingly stringent. Furthermore, we may make numerous statements in our privacy policies and in our marketing materials providing assurances about the security of our data. Should any of these statements prove to be untrue or be perceived as untrue, even through circumstances beyond our reasonable control, we may face claims, investigations or other proceedings by the U.S. Federal Trade Commission, state and foreign regulators, our customers and private litigants.

While we maintain insurance coverage, we cannot assure that such coverage will be adequate or otherwise protect us from or adequately mitigate liabilities or damages with respect to claims, costs, expenses, litigation, fines, penalties, business loss, data loss, regulatory actions or material adverse effects arising out of our

privacy and security practices, or that such coverage will continue to be available on acceptable terms or at all. The successful assertion of one or more large claims against us that exceeds our available insurance coverage, or results in changes to our insurance policies (including premium increases or the imposition of large deductible or co-insurance requirements), could have an adverse effect on our business. In addition, we cannot be sure that our existing insurance coverage will continue to be available on acceptable terms or that our insurers will not deny coverage as to any future claim.

We are heavily dependent on our senior management, and a loss of a member of our senior management team in the future, even if only temporary, could harm our business.

If we lose members of our senior management for a short or an extended time, we may not be able to find appropriate replacements on a timely basis, and our business could be adversely affected. Our existing operations and continued future development depend to a significant extent upon the performance and active participation of certain key individuals, including our chief executive officer, Raju Mohan.

Competition for qualified personnel in the biotechnology and pharmaceuticals industry is intense due to the limited number of individuals who possess the skills and experience required. To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided, and plan to continue providing, equity incentive awards that vest over time. The value to employees of equity incentive awards that vest over time may be significantly affected by movements in our stock price that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. We face significant competition for employees, particularly scientific personnel, from other biopharmaceutical companies, which include both publicly traded and privately held companies, and we may not be able to hire new employees quickly enough to meet our needs. All of our employees are hired on an “at-will” basis, which means that any of our employees could leave our employment at any time, with or without notice. We do not maintain “key man” insurance policies on the lives of these individuals or the lives of any of our other employees. We may not be able to attract and retain quality personnel on acceptable terms, or at all, which may cause our business, financial conditions, results of operations and prospects to suffer.

We will need to grow our size and capabilities, and we may experience difficulties in managing this growth, which could disrupt our operations.

Our operations are dependent upon the services of our executives and our employees who are engaged in research and development. The loss of the services of our executive officers or senior research personnel could delay our product development programs and our research and development efforts. In order to develop our business in accordance with our business plan, we will have to hire additional qualified personnel, including in the areas of research, manufacturing, clinical trials management, regulatory affairs, and sales and marketing. We are continuing our efforts to recruit and hire the necessary employees to support our planned operations in the near term. However, competition for qualified employees among companies in the biotechnology and biopharmaceutical industry is intense, and no assurance can be given that we will be able attract, hire, retain and motivate the highly skilled employees that we need. Future growth will impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our internal development efforts effectively, including the clinical and FDA review process for our product candidates, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems and procedures.

As of , 2021, we had more than full-time employees, compared to full-time employees as of , 2020, and, in connection with the advancement of our development programs and becoming a public company, we expect to increase the number of our employees and the scope of our operations, particularly in the areas of research and clinical development and regulatory affairs. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities, and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expected expansion of our operations or recruit and train additional qualified personnel. Moreover, the expected physical expansion of our operations may lead to significant costs and may divert our management resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations

Our future financial performance and our ability to commercialize our product candidates, if approved, will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain research and clinical development services. There can be no assurance that the services of these independent organizations, advisors and consultants will continue to be available to us on a timely basis, or at all, when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality, compliance or accuracy of the services provided by consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval of our product candidates or otherwise advance our business. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, if at all.

If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and commercialize our product candidates and, accordingly, may not achieve our research, development and commercialization goals on a timely basis, or at all.

If we engage in future acquisitions or strategic partnerships, this may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks.

We may evaluate various acquisitions and strategic partnerships, including licensing or acquiring complementary products, intellectual property rights, technologies or businesses from time to time. Any potential acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption or incurrence of additional indebtedness or contingent liabilities;
- dilution resulting from the issuance of our equity securities;
- assimilation of operations, intellectual property and products of an acquired company or product, including difficulties associated with integrating new personnel;
- acquisition of intangible assets that could results in significant future amortization expenses;
- the diversion of our management's attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition;
- retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and regulatory approvals; and
- our inability to generate revenue from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

Depending on the size and nature of future strategic acquisitions, we may acquire assets or businesses that require us to raise additional capital or to operate or manage businesses in which we have limited experience. Making larger acquisitions that require us to raise additional capital to fund the acquisition will expose us to the risks associated with capital raising activities. Acquiring and thereafter operating larger new businesses will also increase our management, operating and reporting costs and burdens. Moreover, we may not be able to locate suitable acquisition opportunities and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business.

We expect to rely on third parties to perform many essential services for any products, if approved, that we commercialize, including services related to distribution, government price reporting, customer service, accounts receivable management, cash collection and adverse event reporting. If these third parties fail to perform as expected or to comply with legal and regulatory requirements, our ability to

commercialize our current or future product candidates, if any are approved, will be significantly impacted and we may be subject to regulatory sanctions.

We expect to retain third-party service providers to perform a variety of functions related to the sale of our current or future product candidates, if any are approved, key aspects of which will be out of our direct control. These service providers may provide key services related to distribution, customer service, accounts receivable management and cash collection. If we retain a service provider, we will substantially rely on it as well as other third-party providers that perform services for us, including entrusting our inventories of products to their care and handling. If these third-party service providers fail to comply with applicable laws and regulations, fail to meet expected deadlines or otherwise do not carry out their contractual duties to us, or encounter physical or natural damage at their facilities, our ability to deliver product to meet commercial demand would be significantly impaired and we may be subject to regulatory enforcement action.

In addition, we may engage in the future with third parties to perform various other services for us relating to adverse event reporting, safety database management, fulfillment of requests for medical information regarding our product candidates and related services. If the quality or accuracy of the data maintained by these service providers is insufficient, or these third parties otherwise fail to comply with regulatory requirements related to adverse event reporting, then we could be subject to regulatory sanctions.

Additionally, we may contract in the future with a third party to calculate and report pricing information mandated by various government programs. If a third party fails to timely report or adjust prices as required or errs in calculating government pricing information from transactional data in our financial records, then it could impact our discount and rebate liability, and potentially subject us to regulatory sanctions or False Claims Act lawsuits.

We may not be able to obtain or maintain orphan drug designations for certain of our product candidates, and we may be unable to maintain the benefits associated with orphan drug designation, including the potential for market exclusivity.

Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act of 1983, the FDA may designate a product as an orphan product if it is intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals in the United States, or a patient population of greater than 200,000 individuals in the United States, but for which there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the European Union, the European Medicines Agency's, or the EMA's, Committee for Orphan Medicinal Products grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than five in 10,000 persons in the European Union. There can be no assurance that the FDA or the EMA's Committee for Orphan Medicinal Products will grant orphan designation for any indication for which we apply, or that we will be able to maintain such designation.

In the United States, orphan designation entitles a party to financial incentives such as opportunities for grant funding toward clinical trial costs, tax advantages and user-fee waivers. In addition, if a product candidate that has orphan designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications, including an NDA, to market the same drug for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or where the manufacturer is unable to assure sufficient product quantity. The applicable exclusivity period is ten years in Europe, but such exclusivity period can be reduced to six years if a product no longer meets the criteria for orphan designation or if the product is sufficiently profitable so that market exclusivity is no longer justified.

Even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs can be approved for the same condition. Even after an orphan drug is approved, the FDA or comparable foreign regulatory authority can subsequently approve the same drug for the same condition if such regulatory authority concludes that the later drug is clinically superior, if it is shown to be safer, more effective or makes a major contribution to patient care. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process.

Risks Related to Government Regulation

The FDA regulatory approval process is lengthy, time-consuming and unpredictable, and we may experience significant delays in the clinical development and regulatory approval of our product candidates.

We have not previously submitted an NDA to the FDA, or similar approval filings to comparable foreign authorities. NDAs must include extensive preclinical and clinical data and supporting information to establish the product candidate's safety and efficacy for NDAs for each desired indication. Our current beliefs regarding the registration pathway for VTX958 and VTX002, respectively, are based on our interpretation of communications with the FDA to date and our efforts to address such communications, which may be incorrect. Further, enrollment in our trials may need to be further adjusted based on future feedback from the FDA or other regulatory agency input, which could result in significant delays to our currently anticipated timeline for development and approval of our product candidates or prevent their approval entirely.

We may also experience delays, including delays arising from the need to increase enrollment, in completing planned clinical trials for a variety of reasons, including delays related to:

- the availability of financial resources to commence and complete the planned clinical trials;
- reaching agreement on acceptable contract terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining approval at each clinical trial site by an IRB or central IRB;
- recruiting suitable patients to participate in a clinical trial;
- having patients complete a clinical trial or return for post-treatment follow-up;
- clinical trial sites deviating from trial protocol or dropping out of a clinical trial;
- adding new clinical trial sites;
- manufacturing sufficient quantities of qualified materials under cGMP and applying them on a subject by subject basis for use in clinical trials; or
- timely implementing or validating changes to our manufacturing or quality control processes and methods needed to address FDA feedback.

We could also encounter delays if physicians encounter unresolved ethical issues associated with enrolling patients in clinical trials of our product candidates in lieu of prescribing existing treatments that have established safety and efficacy profiles. Further, a clinical trial may be suspended or terminated by us, the IRBs for the institutions in which such trials are being conducted, by the FDA or other regulatory authorities, or recommended for suspension or termination by DSMBs due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. If we experience termination of, or delays in the completion of, any clinical trial of our product candidates, the commercial prospects for our product candidates will be harmed, and our ability to generate product revenue will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product development and approval process and jeopardize our ability to commence product sales and generate revenue.

The clinical and commercial utility of our product candidates are uncertain and may never be realized.

Our product candidates are in the early stages of development. We currently have one ongoing clinical trial to evaluate VTX958. Success in early clinical trials does not ensure that large-scale clinical trials will be successful nor does it predict final results. In addition, we will not be able to treat patients if we cannot manufacture a sufficient quantity of VTX958 or other product candidates that meets our minimum specifications. In addition, VTX958 and VTX002 have only been tested in a small number of patients. Results from these clinical trials may not necessarily be indicative of the safety and tolerability or efficacy of VTX958 and VTX002 as we expand into larger clinical trials.

We may not ultimately be able to provide the FDA with substantial clinical evidence to support a claim of safety or efficacy sufficient to enable the FDA to approve our product candidates for any indication. This may be because later clinical trials fail to reproduce favorable data obtained in earlier clinical trials, because the FDA disagrees with how we interpret the data from these clinical trials or because the FDA does not accept these

therapeutic effects as valid endpoints in pivotal clinical trials necessary for market approval. We will also need to demonstrate that our product candidates are safe. We do not have data on possible harmful long-term effects of our product candidates and do not expect to have this data in the near future. As a result, our ability to generate clinical safety and effectiveness data sufficient to support submission of a marketing application or commercialization of our product candidates is uncertain and is subject to significant risk.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.

In order to market and sell our products outside the United States, we or our third-party collaborators may be required to obtain separate marketing approvals and comply with numerous and varying regulatory requirements. Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. Approval policies and requirements may vary among jurisdictions. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials as clinical studies conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval. We or our collaborators may not be able to file for regulatory approval of our product candidates in international jurisdictions or obtain approvals from regulatory authorities outside the United States on a timely basis, if at all.

We may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our product candidates in certain countries. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

A variety of risks associated with marketing our product candidates internationally could materially adversely affect our business.

We plan to seek regulatory approval of our product candidates outside of the U.S. and, accordingly, we expect that we will be subject to additional risks related to operating in foreign countries if we obtain the necessary approvals, including:

- differing regulatory requirements in foreign countries;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the U.S.;
- differing payor reimbursement regimes, governmental payors or patient self-pay systems, and price controls;
- potential liability under the U.S. Foreign Corrupt Practices Act of 1977 or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the U.S.;

- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad;
- the impact of public health epidemics on the global economy, such as the coronavirus pandemic currently having an impact throughout the world; and
- business interruptions resulting from geo-political actions, including war and terrorism.

These and other risks associated with international operations may materially adversely affect our ability to attain or maintain profitable operations.

We have never commercialized a product candidate before and may lack the necessary expertise, personnel and resources to successfully commercialize any products on our own or together with suitable collaborators.

We have never commercialized a product candidate, and we currently have no sales force, marketing or distribution capabilities. To achieve commercial success for the product candidates, which we may license to others, we will rely on the assistance and guidance of those collaborators. For product candidates for which we retain commercialization rights and marketing approval, we will have to develop our own sales, marketing and supply organization or outsource these activities to a third party.

Factors that may affect our ability to commercialize our product candidates, if approved, on our own include recruiting and retaining adequate numbers of effective sales and marketing personnel, developing adequate educational and marketing programs to increase public acceptance of our approved product candidates, ensuring regulatory compliance of our company, employees and third parties under applicable healthcare laws and other unforeseen costs associated with creating an independent sales and marketing organization. Developing a sales and marketing organization will be expensive and time-consuming and could delay the launch of our product candidates upon approval. We may not be able to build an effective sales and marketing organization. If we are unable to build our own distribution and marketing capabilities or to find suitable partners for the commercialization of our product candidates, we may not generate revenues from them or be able to reach or sustain profitability.

We are, and if we receive regulatory approval of our product candidates, will continue to be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.

Any regulatory approvals that we receive for our product candidates will require surveillance to monitor the safety and efficacy of such product candidates. The FDA may also require a REMS to approve our product candidates, which could entail requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA may also require post-approval Phase 4 studies. Moreover, the FDA and comparable foreign regulatory authorities will continue to closely monitor the safety profile of any product even after approval. If the FDA or comparable foreign regulatory authorities become aware of new safety information after approval of any of our product candidates, they may withdraw approval, require labeling changes or establishment of a REMS or similar strategy, impose significant restrictions on a product's indicated uses or marketing, or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance. Any such restrictions could limit sales of the product.

In addition, we, our contractors, and our collaborators are and will remain responsible for FDA compliance, including requirements related to product design, testing, clinical and pre-clinical trials approval, manufacturing processes and quality, labeling, packaging, distribution, adverse event and deviation reporting, storage, advertising, marketing, promotion, sale, import, export, submissions of safety and other post-marketing information and reports, such as deviation reports, registration, product listing, annual user fees and recordkeeping for our product candidates. We and any of our collaborators, including our contract manufacturers, could be subject to periodic unannounced inspections by the FDA to monitor and ensure compliance with regulatory requirements. Application holders must further notify the FDA, and depending on the nature of the change, obtain FDA pre-approval for product and manufacturing changes. The cost of compliance with post-approval regulations may have a negative effect on our results of operations and financial condition.

Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, that the product candidate is less effective than previously thought,

problems with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing, distribution, or manufacturing of our product candidates, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- imposition of a REMS, which may include distribution or use restrictions;
- requirements to conduct additional post-market clinical trials to assess the safety of the product;
- restrictions on the labeling of our product candidates, including required additional warnings, such as black box warnings, contraindications, precautions and restrictions on the approved indication or use;
- modifications to promotional pieces;
- changes to product labeling or the way the product is administered;
- liability for harm caused to patients or subjects;
- fines, restitution, disgorgement, warning letters, untitled letters or holds on or termination of clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of license approvals;
- product seizure or detention or refusal to permit the import or export of our product candidates;
- injunctions or the imposition of civil or criminal penalties, including imprisonment;
- FDA debarment, debarment from government contracts, and refusal of future orders under existing contracts, exclusion from federal healthcare programs, consent decrees, or corporate integrity agreements;
- regulatory authority issuance of safety alerts, Dear Healthcare Provider letters, press releases, or other communications containing warnings or other safety information about the product candidate;
- reputational harm; or
- the product becoming less competitive.

Any of these events could further have other material and adverse effects on our operations and business and could adversely impact our stock price and could significantly harm our business, financial condition, results of operations, and prospects.

The FDA's and other regulatory authorities' policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, be subject to other regulatory enforcement action, and we may not achieve or sustain profitability.

We are subject to governmental export and import controls that could impair our ability to compete in international markets due to licensing requirements and subject us to liability if we are not in compliance with applicable laws. Compliance with these legal requirements could limit our ability to compete in foreign markets and subject us to liability if we violate them.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations and various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Control. Exports of our product candidates outside of the United States must be made in compliance with these laws and regulations. If we fail to comply with these laws and regulations, we and certain of our employees could be subject to substantial civil or criminal penalties, including the possible loss of export or import privileges; fines, which may be imposed on us and responsible employees or managers; and, in extreme cases, the incarceration of responsible employees or managers.

In addition, changes in our product candidates or changes in applicable export or import laws and regulations may create delays in the introduction, provision or sale of our product candidates in international markets, prevent customers from using our product candidates or, in some cases, prevent the export or import of our product candidates to certain countries, governments or persons altogether. Any limitation on our ability to export, provide or sell our product candidates could adversely affect our business, financial condition and results of operations.

We are subject to U.S. and foreign anti-corruption and anti-money laundering laws with respect to our operations and non-compliance with such laws can subject us to criminal and/or civil liability and harm our business.

We are subject to the U.S. Foreign Corrupt Practices Act of 1977, as amended, or the FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. §201, the U.S. Travel Act, the USA PATRIOT Act and possibly other state and national anti-bribery and anti-money laundering laws in countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, third-party intermediaries, joint venture partners and collaborators from authorizing, promising, offering or providing, directly or indirectly, improper payments or benefits to recipients in the public or private sector. We have used contract research organizations abroad for clinical trials. In addition, we may engage third-party intermediaries to sell our product candidates abroad once we enter a commercialization phase for our product candidates and/or to obtain necessary permits, licenses, and other regulatory approvals. We or our third-party intermediaries may have direct or indirect interactions with officials and employees of government agencies or state-owned or affiliated entities. We can be held liable for the corrupt or other illegal activities of these third-party intermediaries, our employees, representatives, contractors, partners and agents, even if we do not explicitly authorize or have actual knowledge of such activities.

We expect to adopt an anti-corruption policy before the completion of this offering. The anti-corruption policy mandates compliance with the FCPA and other anti-corruption laws applicable to our business throughout the world. However, there can be no assurance that our employees and third-party intermediaries will comply with this policy or such anti-corruption laws. Noncompliance with anti-corruption and anti-money laundering laws could subject us to whistleblower complaints, investigations, sanctions, settlements, prosecution, other investigations or other enforcement actions. If such actions are launched, or governmental or other sanctions are imposed, or if we do not prevail in any possible civil or criminal litigation, our business, results of operations and financial condition could be materially harmed. In addition, responding to any action will likely result in a materially significant diversion of management's attention and resources and significant defense and compliance costs and other professional fees. In certain cases, enforcement authorities may even cause us to appoint an independent compliance monitor, which can result in added costs and administrative burdens.

If we fail to comply with environmental, health, and safety laws and regulations, including regulations governing the handling, storage or disposal of hazardous materials, we could become subject to fines or penalties or incur costs that could harm our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous materials, including chemicals and biological materials. Our operations also may produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We will not be able to eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from any use by us of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological or hazardous materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Changes in funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept payment of user fees

and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the FDA, the Securities and Exchange Commission, or the SEC, and other government agencies on which our operations may rely is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. In response to the COVID-19 pandemic, the FDA recently announced that it will continue to postpone domestic and foreign routine surveillance inspections due to COVID-19. While the FDA indicated that it would consider alternative methods for inspections and could exercise discretion on a case-by-case basis to approve products based on a desk review, if a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could potentially impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

If we fail to comply with applicable federal and state healthcare laws, including FDA, healthcare fraud and abuse, pharmaceutical marketing and advertising, and information privacy and security laws, we could face substantial penalties and our business, financial condition, results of operations, and prospects could be adversely affected.

As a biopharmaceutical company, we, as well as any of our contractors who conduct business for or on our behalf, are subject to many federal and state healthcare laws, including the federal Anti-Kickback Statute, or AKS, the federal civil and criminal False Claims Act, or FCA, the Civil Monetary Penalties Statute, the Medicaid Drug Rebate statute and other price reporting requirements, the federal Physician Payment Sunshine Act, the Veterans Health Care Act of 1992, HIPAA (as amended by the Health Information Technology for Economics and Clinical Health Act), the U.S. Foreign Corrupt Practices Act of 1977, the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2020, or collectively, the ACA, and similar state laws. Even though we do not make referrals of healthcare services or bill directly to Medicare, Medicaid, or other third-party payors, certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. If we do not comply with all applicable fraud and abuse laws, we may be subject to healthcare fraud and abuse enforcement by both the federal government and the states in which we conduct our business.

Laws and regulations require calculation and reporting of complex pricing information for prescription drugs, and compliance will require us to invest in significant resources and develop a price reporting infrastructure, or depend on third parties to compute and report our drug pricing. Pricing reported to the Centers for Medicare & Medicaid Services, or CMS, must be certified. Non-compliant activities expose us to FCA risk if they result in overcharging agencies, underpaying rebates to agencies, or causing agencies to overpay providers.

If we or our operations are found to be in violation of any federal or state healthcare law, or any other governmental regulations that apply to us, we may be subject to significant penalties, including civil, criminal, and administrative penalties, damages, fines, disgorgement, debarment from government contracts, refusal of orders under existing contracts, exclusion from participation in U.S. federal or state health care programs, corporate integrity agreements and the curtailment or restructuring of our operations, any of which could materially adversely affect our ability to operate our business and our financial results. If any of the physicians or other healthcare providers or entities with whom we expect to do business, including our collaborators, is found not to be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including, but not limited to, exclusions from participation in government healthcare programs, which could also materially affect our business.

In particular, if we are found to have impermissibly promoted any of our product candidates, we may become subject to significant liability and government fines. We, and any of our collaborators, must comply with requirements concerning advertising and promotion for any of our product candidates for which we or they obtain marketing approval. Promotional communications with respect to therapeutics are subject to a variety of legal and regulatory restrictions and continuing review by the FDA, Department of Justice, Department of Health and Human Services' Office of Inspector General, state attorneys general, members of Congress, and the public. When the FDA or comparable foreign regulatory authorities issue regulatory approval for a product candidate, the regulatory approval is limited to those specific uses and indications for which a product candidate is approved. If we are not able to obtain FDA approval for desired uses or indications for our product

candidates, we may not market or promote our product candidates for those indications and uses, referred to as off-label uses, and our business may be adversely affected. We further must be able to sufficiently substantiate any claims that we make for our product candidates, including claims comparing our products candidates to other companies' products and must abide by the FDA's strict requirements regarding the content of promotion and advertising.

While physicians may choose to prescribe products for uses that are not described in the product's labeling and for uses that differ from those tested in clinical trials and approved by the regulatory authorities, we are prohibited from marketing and promoting our product candidates for indications and uses that are not specifically approved by the FDA. These off-label uses are common across medical specialties and may constitute an appropriate treatment for some patients in varied circumstances. Regulatory authorities in the United States generally do not restrict or regulate the behavior of physicians in their choice of treatment within the practice of medicine. Regulatory authorities do, however, restrict communications by biopharmaceutical companies concerning off-label use.

The FDA and other agencies actively enforce the laws and regulations regarding product promotion, particularly those prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted a product may be subject to significant sanctions. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees of permanent injunctions under which specified promotional conduct is changed or curtailed. Thus, we and any of our collaborators will not be able to promote any product candidates we develop for indications or uses for which they are not approved.

In the United States, engaging in the impermissible promotion of our product candidates, following approval, for off-label uses can also subject us to false claims and other litigation under federal and state statutes, including fraud and abuse and consumer protection laws, which can lead to significant civil and criminal penalties and fines, agreements with governmental authorities that materially restrict the manner in which we promote or distribute our product candidates and do business through, for example, corporate integrity agreements, suspension or exclusion from participation in federal and state healthcare programs, and debarment from government contracts and refusal of future orders under existing contracts. These false claims statutes include the FCA, which allows any individual to bring a lawsuit against a biopharmaceutical company on behalf of the federal government alleging submission of false or fraudulent claims or causing others to present such false or fraudulent claims, for payment by a federal program such as Medicare or Medicaid. If the government decides to intervene and prevails in the lawsuit, the individual will share in the proceeds from any fines or settlement funds. If the government declines to intervene, the individual may pursue the case alone. These FCA lawsuits against manufacturers of drugs and biologics have increased significantly in volume and breadth, leading to several substantial civil and criminal settlements in the hundreds of millions or billions of dollars, pertaining to certain sales practices and promoting off-label uses. In addition, FCA lawsuits may expose manufacturers to follow-on claims by private payors based on fraudulent marketing practices. This growth in litigation has increased the risk that a biopharmaceutical company will have to defend a false claim action, pay settlement fines or restitution, as well as criminal and civil penalties, agree to comply with burdensome reporting and compliance obligations, and be excluded from Medicare, Medicaid, or other federal and state healthcare programs. If we or our future collaborators do not lawfully promote our approved product candidates, if any, we may become subject to such litigation and, if we do not successfully defend against such actions, those actions may have a material adverse effect on our business, financial condition, results of operations and prospects.

Although an effective compliance program can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Moreover, achieving and sustaining compliance with applicable federal and state fraud laws may prove costly. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business.

Coverage and reimbursement may be limited or unavailable in certain market segments for our product candidates, which could make it difficult for us to sell our product candidates profitably.

In both domestic and foreign markets, sales of our product candidates, if approved, depend on the availability of coverage and adequate reimbursement from third-party payors. Such third-party payors include government health programs such as Medicare and Medicaid, managed care providers, private health insurers and other organizations.

Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Obtaining coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance.

Government authorities and third-party payors decide which drugs and treatments they will cover and the amount of reimbursement. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. If reimbursement is not available, or is available only to limited levels, our product candidates may be competitively disadvantaged, and we, or our collaborators, may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us, or our collaborators, to establish or maintain a market share sufficient to realize a sufficient return on our or their investments. Alternatively, securing favorable reimbursement terms may require us to compromise pricing and prevent us from realizing an adequate margin over cost. Reimbursement by a third-party payor may depend upon a number of factors, including, but not limited to, the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to the payor supporting scientific, clinical and cost-effectiveness data for the use of our product candidates. Even if we obtain coverage for a given product candidate, the resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Moreover, the factors noted above have continued to be the focus of policy and regulatory debate that has, thus far, shown the potential for movement towards permanent policy changes; this trend is likely to continue, and may result in more or less favorable impacts on pricing. Patients are unlikely to use our product candidates, unless coverage is provided, and reimbursement is adequate to cover a significant portion of the cost of our product candidates.

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained.

Prices paid for a drug also vary depending on the class of trade. Prices charged to government customers are subject to price controls, including ceilings, and private institutions obtain discounts through group purchasing organizations. Net prices for drugs may be further reduced by mandatory discounts or rebates required by government healthcare programs and demanded by private payors. It is also not uncommon for market conditions to warrant multiple discounts to different customers on the same unit, such as purchase discounts to institutional care providers and rebates to the health plans that pay them, which reduces the net realization on the original sale.

In addition, federal programs impose penalties on manufacturers of drugs marketed under an NDA, in the form of mandatory additional rebates and/or discounts if commercial prices increase at a rate greater than the Consumer Price Index-Urban, and these rebates and/or discounts, which can be substantial, may impact our ability to raise commercial prices. Regulatory authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications, which could affect our ability or that of our collaborators to sell our product candidates profitably. These payors may not view our product candidates, if any, as cost-effective, and coverage and reimbursement may not be available to our customers, or those of our collaborators, or may not be sufficient to allow our product candidates, if any, to be marketed on a competitive basis. Cost control initiatives could cause us, or our collaborators, to decrease, discount, or rebate a portion of the price we, or they, might establish for our product candidates, which could result in lower than anticipated product revenues. If the realized prices for our product candidates, if any, decrease or if governmental and other third-party payors do not provide adequate coverage or reimbursement, our prospects

for revenue and profitability will suffer. Moreover, the recent and ongoing series of congressional hearings relating to drug pricing has presented heightened attention to the biopharmaceutical industry, creating the potential for political and public pressure, while the potential for resulting legislative or policy changes presents uncertainty.

Assuming coverage is approved, the resulting reimbursement payment rates might not be adequate. If payors subject our product candidates to maximum payment amounts or impose limitations that make it difficult to obtain reimbursement, providers may choose to use therapies, which are less expensive when compared to our product candidates. Additionally, if payors require high copayments, beneficiaries may decline prescriptions and seek alternative therapies. We may need to conduct post-marketing studies in order to demonstrate the cost-effectiveness of any future products to the satisfaction of hospitals and other target customers and their third-party payors. Such studies might require us to commit a significant amount of management time and financial and other resources. Our future products might not ultimately be considered cost-effective. Adequate third-party coverage and reimbursement might not be available to enable us to maintain price levels sufficient to realize an appropriate return on investment in product development.

Third-party payors, whether domestic or foreign, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In addition, third-party payors are requiring higher levels of evidence of the benefits and clinical outcomes of new technologies and are challenging the prices charged. We, and our collaborators, cannot be sure that coverage will be available for any product candidate that we, or they, commercialize and, if available, that the reimbursement rates will be adequate. Further, the net reimbursement for drug products may be subject to additional reductions if there are changes to laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. An inability to promptly obtain coverage and adequate payment rates from both government-funded and private payors for any of our product candidates for which we obtain marketing approval could have a material adverse effect on our results of operations, our ability to raise capital needed to commercialize products, and our overall financial condition.

There have been, and likely will continue to be, legislative and regulatory proposals at the federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our product candidates, if we obtain regulatory approval;
- our ability to set a price that we believe is fair for our product candidates;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors, which may adversely affect our future profitability.

We are subject to new legislation, regulatory proposals and healthcare payor initiatives that may increase our costs of compliance, and adversely affect our ability to market our products, obtain collaborators and raise capital.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities, and affect our ability, or the ability of our collaborators, to profitably sell any product candidates for which we obtain marketing approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we, or our collaborators, may receive for any approved product candidates.

Since its enactment, there have been executive, judicial and Congressional challenges to certain aspects of the ACA. For example, in June 2021 the U.S. Supreme Court held that Texas and other challengers had no legal standing to challenge the ACA, dismissing the case on procedural grounds without specifically ruling on the constitutionality of the ACA. Thus, the ACA will remain in effect in its current form. Further, prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace, which

began on February 15, 2021 and remained open through August 15, 2021. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including, among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how such challenges and healthcare measures initiated by the Biden administration will impact the ACA, our business, financial condition and results of operations. Complying with any new legislation or change in regulatory requirements could be time-intensive and expensive, resulting in a material adverse effect on our business.

Additional federal and state healthcare reform measures may be adopted in the future that may result in more rigorous coverage criteria, increased regulatory burdens and operating costs, decreased net revenue from our biopharmaceutical products, decreased potential returns from our development efforts, and additional downward pressure on the price that we receive for any approved drug. For example, under the American Rescue Plan of 2021, effective January 1, 2021, the statutory cap on Medicaid Drug Rebate Program rebates that manufacturers pay to state Medicaid programs will be eliminated. Elimination of this cap may require pharmaceutical manufacturers to pay more in rebates than it receives on the sale of products, which could have a material impact on our business. Further any reduction in reimbursement from Medicare or other government healthcare programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our product candidates.

Legislative and regulatory proposals may also be made to expand post-approval requirements and restrict sales and promotional activities for drugs. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance, or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

In addition, there have been a number of other policy, legislative and regulatory proposals aimed at changing the pharmaceutical industry, including heightened governmental scrutiny over the manner in which drug manufacturers set prices for their marketed products, U.S. Congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. Additionally, based on a recent executive order, the Biden administration expressed its intent to pursue certain policy initiatives to reduce drug prices. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Any reduction in reimbursement from Medicare or other government programs may result in a reduction in payments from private payors.

We are unable to predict the future course of federal or state healthcare legislation in the United States directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. The ACA and any further changes in the law or regulatory framework that reduce our revenue or increase our costs could also have a material and adverse effect on our business, financial condition and results of operations.

Governments outside the United States tend to impose strict price controls, which may adversely affect our revenues, if any.

In international markets, reimbursement and health care payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. In some countries, particularly the countries of the EU, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain coverage and reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. There can be no assurance that our product candidates will be considered cost-effective by third-party payors, that an adequate level of reimbursement will be available, or that the third-party payors' reimbursement policies will not adversely affect our ability to sell our product

candidates profitably. If reimbursement of our product candidates is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed, possibly materially.

If our employees, independent contractors, consultants, commercial partners or vendors engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, we, directly or indirectly, could be exposed to significant losses and liability, including, among other things, criminal sanctions, civil penalties, contractual damages, exclusion from governmental healthcare programs, reputational harm, administrative burdens and diminished profits and future earnings.

We are exposed to the risk of employee fraud or other illegal activity by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and/or negligent conduct that fails to comply with the laws of the FDA and other similar foreign regulatory bodies, provide true, complete and accurate information to the FDA and other similar foreign regulatory bodies, comply with manufacturing standards we have established, comply with healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws, or report financial information or data accurately or to disclose unauthorized activities to us. If we obtain FDA approval of any of our product candidates and begin commercializing those products in the United States, our potential exposure under such laws will increase significantly, and our costs associated with compliance with such laws are also likely to increase. These laws may impact, among other things, our current activities with principal investigators and research patients, as well as proposed and future sales, marketing and education programs. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commissions, certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials.

We will adopt a Code of Conduct and Ethics before the completion of this offering, but it is not always possible to identify and deter misconduct or other improper activities by our employees or third parties that we engage for our business operations, including independent contractors, consultants, commercial collaborators, principal investigators, CROs, suppliers and vendors, and the precautions we take to detect and prevent inappropriate conduct may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws or regulations. Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our, or our employees', consultants', collaborators', contractors', or vendors' business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, compliance agreements, withdrawal of product approvals, and curtailment of our operations, among other things, any of which could adversely affect our ability to operate our business and our results of operations. In addition, the approval and commercialization of any of our product candidates outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

Risks Related to Intellectual Property

If we are unable to obtain and maintain sufficient intellectual property protection for our product candidates, or if the scope of the intellectual property protection is not sufficiently broad, we may not be able to compete effectively or operate profitably.

We rely upon a combination of patents, know-how and confidentiality agreements to protect the intellectual property related to our product candidates and to prevent third parties from copying and surpassing our achievements, thus eroding our competitive position in our market.

Our success is dependent in large part on our obtaining, maintaining, protecting and enforcing patents and other proprietary rights in the United States and other countries with respect to our product candidates and on our ability to avoid infringing the intellectual property and other proprietary rights of others. Furthermore, patent law relating to the scope of claims in the biotechnology field in which we operate is still evolving and,

consequently, patent positions in our industry may not be as strong as in other more well-established fields. No consistent policy regarding the breadth of claims allowed in biotechnology patents has emerged to date.

We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our product candidates and novel discoveries that are important to our business. Our pending and future patent applications may not result in patents being issued or issued patents may not afford sufficient protection of our product candidates or their intended uses against competitors, nor can there be any assurance that the patents issued will not be infringed, designed around, invalidated by third parties, or effectively prevent others from commercializing competitive products.

Obtaining and enforcing patents is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications or maintain and/or enforce patents that may issue based on our patent applications, at a reasonable cost or in a timely manner, including delays as a result of the COVID-19 pandemic impacting our operations. It is also possible that we will fail to identify patentable aspects of our research and development results before it is too late to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, contract research organizations, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach these agreements and disclose such results before a patent application is filed, thereby jeopardizing our ability to seek patent protection.

Composition of matter patents for pharmaceutical product candidates often provide a strong form of intellectual property protection for those types of products, as such patents provide protection without regard to any method of use. We cannot be certain that the claims in our pending patent applications directed to composition of matter of our product candidates will be considered patentable by the United States Patent and Trademark Office (USPTO) or by patent offices in foreign countries, or that the claims in any of our issued patents will be considered valid and enforceable by courts in the United States or foreign countries. Method of use patents protect the use of a product for the specified method. This type of patent does not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their products for our targeted indications, physicians may prescribe these products “off-label.” Although off-label prescriptions may infringe or contribute to the infringement of method of use patents, the practice is common and such infringement is difficult to prevent or prosecute.

The patent position of biopharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation, resulting in court decisions, including Supreme Court decisions, which have increased uncertainties as to the ability to enforce patent rights in the future. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States, or vice versa.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our potential future collaborators will be successful in protecting our product candidates by obtaining and defending patents. For example, we may not be aware of all third-party intellectual property rights potentially relating to our product candidates or their intended uses, and as a result the impact of such third-party intellectual property rights upon the patentability of our own patents and patent applications, as well as the impact of such third-party intellectual property upon our freedom to operate, is highly uncertain. Patent applications in the United States and other jurisdictions are typically not published until 18 months after filing or, in some cases, not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, inventorship, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending patent applications may be challenged in patent offices in the United States and abroad. Even issued patents may later be found invalid or unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. For example, our pending patent applications may be subject to third-party pre-issuance submissions of prior art to the USPTO or our issued patents may be subject to post-grant review (PGR) proceedings, oppositions, derivations, reexaminations, or *inter partes* review (IPR) proceedings, in the United States or elsewhere, challenging our patent rights or the patent rights of others. An adverse determination in any such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated, or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical products, or limit the duration of the patent protection of our product candidates. In addition,

given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such candidates are commercialized. The degree of future protection for our proprietary rights is uncertain. Only limited protection may be available and may not adequately protect our rights or permit us to gain or keep any competitive advantage. Any failure to obtain or maintain patent protection with respect to our product candidates or their uses could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. We may also rely on trade secret protection as temporary protection for concepts that may be included in a future patent filing. However, trade secret protection will not protect us from innovations that a competitor develops independently of our proprietary know how. If a competitor independently develops a technology that we protect as a trade secret and files a patent application on that technology, then we may not be able to patent that technology in the future, may require a license from the competitor to use our own know-how, and if the license is not available on commercially-viable terms, then we may not be able to launch our product candidate. Although we require all of our employees to assign their inventions to us, and require all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Furthermore, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, we will not be able to establish or maintain a competitive advantage in our market, and this scenario could materially adversely affect our business, financial condition and results of operations.

We cannot ensure that patent rights relating to inventions described and claimed in our pending patent applications will issue or that patents based on our patent applications will not be challenged and rendered invalid and/or unenforceable.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our potential future collaborators will be successful in protecting our product candidates by obtaining and defending patents. We have pending U.S. and foreign patent applications in our portfolio; however, we cannot predict:

- if and when patents may issue based on our patent applications;
- the scope of protection of any patent issuing based on our patent applications;
- whether the claims of any patent issuing based on our patent applications will provide protection against competitors;
- whether or not third parties will find ways to invalidate or circumvent our patent rights;
- whether or not others will obtain patents claiming aspects similar to those covered by our patents and patent applications;
- whether we will need to initiate litigation or administrative proceedings to enforce and/or defend our patent rights which will be costly whether we win or lose;
- whether the patent applications that we own will result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other foreign countries; and/or
- whether, as the COVID-19 pandemic continues to spread around the globe, we may experience patent office interruption or delays to our ability to timely secure patent coverage to our product candidates.

We cannot be certain that the claims in our pending patent applications directed to our product candidates will be considered patentable by the USPTO or by patent offices in foreign countries. There can be no assurance that any such patent applications will issue as granted patents. One aspect of the determination of patentability of our inventions depends on the scope and content of the “prior art,” information that was or is deemed available to a person of skill in the relevant art prior to the priority date of the claimed invention. There may be prior art of which we are not aware that may affect the patentability of our patent claims or, if issued, affect the validity or enforceability of a patent claim. Even if the patents do issue based on our patent applications, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being

narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, patents in our portfolio may not adequately exclude third parties from practicing relevant technology or prevent others from designing around our claims. If the breadth or strength of our intellectual property position with respect to our product candidates is threatened, it could dissuade companies from collaborating with us to develop and threaten our ability to commercialize our product candidates. In the event of litigation or administrative proceedings, we cannot be certain that the claims in any of our issued patents will be considered valid by courts in the United States or foreign countries.

We may not be able to protect our intellectual property rights throughout the world.

Patents are of national or regional effect, and although we currently have an issued patent and pending applications in the United States, filing, prosecuting and defending patents on all of our product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These competitor products may compete with our product candidates, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Various companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of many countries do not favor the enforcement of patents and other intellectual property protection, particularly those relating to pharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights.

Various countries outside the United States have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. As a result, a patent owner may have limited remedies in certain circumstances, which could materially diminish the value of such patent. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Further, the standards applied by the USPTO and foreign patent offices in granting patents are not always applied uniformly or predictably. As such, we do not know the degree of future protection that we will have on our product candidates. While we will endeavor to try to protect our product candidates with intellectual property rights, such as patents, as appropriate, the process of obtaining patents is time consuming, expensive and unpredictable.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make product candidates that are similar to ours, but that are not covered by the claims of the patents that we own;
- we or future collaborators might not have been the first to make the inventions covered by the issued patent or pending patent application that we own;
- we or future collaborators might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that noncompliance with the USPTO and foreign governmental patent agencies requirement for a number of procedural, documentary, fee payment and other provisions during the

patent process can result in abandonment or lapse of a patent or patent application, and partial or complete loss of patent rights in the relevant jurisdiction;

- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own may be revoked, modified or held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- we cannot predict the scope of protection of any patent issuing based on our patent applications, including whether the patent applications that we own will result in issued patents with claims directed to our product candidates or uses thereof in the United States or in other foreign countries;
- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns;
- countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop and market competing product candidates;
- the claims of any patent issuing based on our patent applications may not provide protection against competitors or any competitive advantages, or may be challenged by third parties;
- if enforced, a court may not hold that our patents are valid, enforceable and infringed;
- we may need to initiate litigation or administrative proceedings to enforce and/or defend our patent rights which will be costly whether we win or lose;
- we may choose not to file a patent application in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent application covering such intellectual property;
- we may fail to adequately protect and police our trademarks and trade secrets; and
- the patents of others may have an adverse effect on our business, including if others obtain patents claiming subject matter similar to or improving that covered by our patents and patent applications.

If any of these or similar events occur, then they could significantly harm our business, results of operations and prospects.

We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent, which might adversely affect our ability to develop and market our products.

As the biopharmaceutical industry expands and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties. There can be no assurance that our operations do not, or will not in the future, infringe existing or future third-party patents. Identification of third-party patent rights that may be relevant to our operations is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction.

Numerous U.S. and foreign patents and pending patent applications exist in our market that are owned by third parties. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with our ability to make, use and sell our product candidates. We do not always conduct independent reviews of pending patent applications of and patents issued to third parties. Patent applications in the United States and elsewhere are typically published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Certain U.S. applications that will not be filed outside the U.S. can remain confidential until patents issue. In addition, patent applications in the United States and elsewhere can be pending for many years before issuance, or unintentionally abandoned patents or applications can be revived. Furthermore, pending patent applications

that have been published can, subject to certain limitations, be later amended in a manner that could cover our product candidates or the use of our product candidates. As such, there may be applications of others now pending or recently revived patents of which we are unaware. These patent applications may later result in issued patents, or the revival of previously abandoned patents, that will prevent, limit or otherwise interfere with our ability to make, use or sell our product candidates.

The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect. For example, we may incorrectly determine that our product candidates are not covered by a third-party patent or may incorrectly predict whether a third-party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our product candidates.

We cannot provide any assurances that third-party patents do not exist which might be enforced against our current technology, including our research programs, product candidates, their respective methods of use, manufacture and formulations thereof, and could result in either an injunction prohibiting our manufacture or future sales, or, with respect to our future sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties, which could be significant.

We may be involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time-consuming and unsuccessful.

Competitors or other third parties may infringe our patents, trademarks or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming and divert the time and attention of our management and scientific personnel. Our pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents, in addition to counterclaims asserting that our patents are invalid or unenforceable, or both. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement or insufficient written description. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. The outcome following legal assertions of invalidity and unenforceability is unpredictable. In any patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention, or decide that the other party's use of our patented technology falls under the safe harbor to patent infringement under 35 U.S.C. §271(e)(1). An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitors and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of our common stock. Moreover, we cannot assure you that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings.

Because of the expense and uncertainty of litigation, we may not be in a position to enforce our intellectual property rights against third parties.

Because of the expense and uncertainty of litigation, we may conclude that even if a third-party is infringing our issued patent, any patents that may be issued as a result of our pending or future patent applications or other intellectual property rights, the risk-adjusted cost of bringing and enforcing such a claim or action may be too high or not in the best interest of our company or our stockholders, or it may be otherwise impractical or undesirable to enforce our intellectual property against some third parties. Our competitors or other third parties may be able to sustain the costs of complex patent litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. In such cases, we may decide that the more prudent course of action is to simply monitor the situation or initiate or seek some other non-litigious action or solution. In addition, the uncertainties associated with litigation could compromise our ability to raise the funds necessary to continue our clinical trials, continue our internal research programs, in-license needed technology or other product candidates, or enter into development partnerships that would help us bring our product candidates to market.

If we are sued for infringing intellectual property rights of third parties, such litigation could be costly and time consuming and could prevent or delay us from developing or commercializing our product candidates.

Our commercial success depends, in part, on our ability to develop, manufacture, market and sell our product candidates without infringing the intellectual property and other proprietary rights of third parties. Third parties may allege that we have infringed or misappropriated their intellectual property. Litigation or other legal proceedings relating to intellectual property claims, with or without merit, is unpredictable and generally expensive and time consuming and, even if resolved in our favor, is likely to divert significant resources from our core business, including distracting our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the market price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

There is a substantial amount of intellectual property litigation in the biotechnology and pharmaceutical industries, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to our products candidates. We cannot be certain that our product candidates will not infringe existing or future patents owned by third parties. Third parties may assert infringement claims against us based on existing or future intellectual property rights. We may decide in the future to seek a license to those third-party intellectual property patents, but we might not be able to do so on reasonable terms. Proving invalidity may be difficult. For example, in the United States, proving invalidity in court requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. If we are found to infringe a third party's intellectual property rights, we could be forced, including by court order, to cease developing, manufacturing or commercializing the infringing product candidate. Alternatively, we may be required to obtain a license from such third party in order to use the infringing technology and continue developing, manufacturing or marketing the infringing product candidate. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business.

We may not be aware of patents that have already been issued and that a third party, for example, a competitor in the fields in which we are developing our product candidates, might assert are infringed by our current or future product candidates, including claims to compositions, formulations, methods of manufacture or methods of use or treatment that cover our product candidates. It is also possible that patents owned by third parties of which we are aware, but which we do not believe are relevant to our product candidates, could be

found to be infringed by our product candidates. In addition, because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our product candidates may infringe. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with our ability to make, use and sell our product candidates. The pharmaceutical and biotechnology industries have produced a considerable number of patents, and it may not always be clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we were sued for patent infringement, we would need to demonstrate that our product candidates or methods of use either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be able to do this. Proving invalidity may be difficult. For example, in the United States, proving invalidity in court requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents, and there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could have a material adverse effect on our business and operations. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. In addition, we may not have sufficient resources to bring these actions to a successful conclusion.

We may choose to challenge the enforceability or validity of claims in a third party's U.S. patent by requesting that the USPTO review the patent claims in an *ex-parte* re-exam, *inter partes* review or post-grant review proceedings. These proceedings are expensive and may consume our time or other resources. We may choose to challenge a third party's patent in patent opposition proceedings in the EPO, or other foreign patent office. The costs of these opposition proceedings could be substantial and may consume our time or other resources. If we fail to obtain a favorable result at the USPTO, EPO or other patent office then we may be exposed to litigation by a third party alleging that the patent may be infringed by our product candidates.

If we are found to infringe a third-party's intellectual property rights, we could be forced, including by court order, to cease developing, manufacturing or commercializing the infringing product candidate. Alternatively, we may be required to obtain a license from such third-party in order to use the infringing technology and continue developing, manufacturing or marketing the infringing product candidate. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, and could divert the time and attention of our technical personnel and management, cause development delays, and/or require us to develop non-infringing technology, which may not be possible on a cost-effective basis, any of which could materially harm our business. In the event of a successful claim of infringement against us, we may have to pay substantial monetary damages, including treble damages and attorneys' fees for willful infringement, pay royalties and other fees, redesign our infringing drug or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and patent applications are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of a patent. The USPTO and various foreign governmental patent agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of

fees and failure to properly legalize and submit formal documents. In such an event, our competitors might be able to enter the market with similar or identical products, which would have a material adverse impact on our business, financial condition, results of operations and prospects.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with other biopharmaceutical companies, our success is dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve both technological and legal complexity, and is therefore costly, time-consuming and inherently uncertain. In addition, the United States has recently enacted and is currently implementing wide-ranging patent reform legislation. Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith America Invents Act, or the America Invents Act, enacted in September 2011, the United States transitioned to a first-to-file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. A third party that files a patent application in the USPTO after March 2013, but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This will require us to be cognizant of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we were the first to either file any patent application related to our product candidates or other technologies or invent any of the inventions claimed in our patents or patent applications.

The America Invents Act also includes a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO-administered post-grant proceedings, including post-grant review, *inter partes* review, and derivation proceedings. Further, because of a lower evidentiary standard in these USPTO post-grant proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Thus, Therefore, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our owned patent applications and the enforcement or defense of our owned issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Additionally, recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. While we do not believe that any of the patents owned by us will be found invalid based on the foregoing, we cannot predict how future decisions by the courts, the U.S. Congress or the USPTO may impact the value of our patents.

We may be subject to claims that we have wrongfully hired an employee from a competitor or that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

As is common in the pharmaceutical industry, in addition to our employees, we engage the services of consultants to assist us in the development of our product candidates. Many of these consultants, and many of our employees, were previously employed at, or may have previously provided or may be currently providing consulting services to, other pharmaceutical companies, including our competitors or potential competitors. We could in the future be subject to claims that we or our employees have inadvertently or otherwise used or disclosed alleged trade secrets or other confidential information of former employers or competitors. Although we try to ensure that our employees and consultants do not use the intellectual property, proprietary information, know-how or trade secrets of others in their work for us, we may become subject to claims that we

caused an employee to breach the terms of his or her non-competition or non-solicitation agreement, or that we or these individuals have, inadvertently or otherwise, used or disclosed the alleged trade secrets or other proprietary information of a former employer or competitor.

While we may litigate to defend ourselves against these claims, even if we are successful, litigation could result in substantial costs and could be a distraction to management. If our defenses to these claims fail, in addition to requiring us to pay monetary damages, a court could prohibit us from using technologies or features that are essential to our product candidates, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. Moreover, any such litigation or the threat thereof may adversely affect our reputation, our ability to form strategic alliances or sublicense our rights to collaborators, engage with scientific advisors or hire employees or consultants, each of which would have an adverse effect on our business, results of operations and financial condition. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

We may not be able to license or acquire new or necessary intellectual property rights or technology from third parties.

Other parties, including our competitors, may have patents and have filed and are likely filing patent applications potentially relevant to our business. In order to avoid infringing these patents, we may find it necessary or prudent to obtain licenses to such patents from such parties. The licensing or acquisition of intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. No assurance can be given that we will be successful in licensing any additional rights or technologies from third parties. Our inability to license the rights and technologies that we have identified, or that we may in the future identify, could have a material adverse impact on our ability to complete the development of our product candidates or to develop additional product candidates. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. Failure to obtain any necessary rights or licenses may detrimentally affect our planned development of our current or future product candidates and could increase the cost, and extend the timelines associated with our development, of such other product candidates, and we may have to abandon development of the relevant program or product candidate. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.

Patent rights are of limited duration. In the United States, if all maintenance fees are paid timely, the natural expiration of a patent is generally 20 years after its first effective filing date. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such product candidates are commercialized. Even if patents covering our product candidates are obtained, once the patent life has expired for a product, we may be open to competition from biosimilar or generic products. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing product candidates similar or identical to ours. Upon issuance in the United States, the term of a patent can be increased by patent term adjustment, which is based on certain delays caused by the USPTO, but this increase can be reduced or eliminated based on certain delays caused by the patent applicant during patent prosecution. The term of a United States patent may also be shortened if the patent is terminally disclaimed over an earlier-filed patent. A patent term extension (PTE) based on regulatory delay may be available in the United States. However, only a single patent can be extended for each marketing approval, and any patent can be extended only once, for a single product. Moreover, the scope of protection during the period of the PTE does not extend to the full scope of the claim, but instead only to the scope of the product as approved. Laws governing analogous PTEs in foreign jurisdictions vary widely, as do laws governing the ability to obtain multiple patents from a single patent family. Additionally, we may not receive an extension if we fail to exercise due diligence during the testing phase or regulatory review process, apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. If we are unable to obtain PTE or restoration, or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our product will be shortened and our competitors may obtain approval of competing products following our

patent expiration and may take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data to launch their product earlier than might otherwise be the case, and our revenue could be reduced, possibly materially.

We may become subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

We may be subject to claims that former employees, collaborators or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor. The failure to name the proper inventors on a patent application can result in the patents issuing thereon being unenforceable. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third parties involved in developing our product candidates or as a result of questions regarding co-ownership of potential joint inventions. Litigation may be necessary to resolve these and other claims challenging inventorship and/or ownership. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Our inventors may have performed work for other portfolio companies as part of their employment with Kalika Biosciences, Inc., or Kalika. While Kalika previously had a services agreement in place with each of its portfolio companies, which included the segregation of services and ownership of intellectual property for each portfolio company, including the ability of inventors to assign inventions, work product and intellectual property directly to us, disputes about ownership between us and Kalika and/or other portfolio companies of Kalika may arise in the future, which may have a material adverse effect on our business.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations and prospects.

Our reliance on third parties can also present intellectual property-related risks. For example, collaborators may not properly obtain, maintain, enforce or defend intellectual property or proprietary rights relating to our product candidates or may use our proprietary information in such a way as to expose us to potential litigation or other intellectual property-related proceedings, including proceedings challenging the scope, ownership, validity and enforceability of our intellectual property. Collaborators may also own or co-own intellectual property covering our product candidates that results from our collaboration with them, and in such cases, we may not have the exclusive right to commercialize such intellectual property or such product candidates. Collaborators may also gain access to our trade secrets or formulations and impact our ability to commercialize our product candidates. We may also need the cooperation of our collaborators to enforce or defend any intellectual property we contribute to or that arises out of our collaborations, which may not be provided to us.

We may rely on trade secrets and proprietary know-how which can be difficult to trace and enforce and, if we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patents for our product candidates, we may also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. Elements of our product candidates, including processes for their preparation and manufacture, may involve proprietary know-how, information or technology that is not covered by patents, and thus for these aspects we may consider trade secrets and know-how to be our primary intellectual property. Any disclosure, either intentional or unintentional, by our employees, the employees of third parties with whom we share our facilities or third-party consultants and vendors that we engage to perform research, clinical trials or manufacturing activities, or misappropriation by third parties (such as through a cybersecurity breach) of our trade secrets or proprietary information could enable competitors to duplicate or surpass our technological achievements, thus eroding our competitive position in our market. Because we expect to rely on third parties in the development

and manufacture of our product candidates, we must, at times, share trade secrets with them. Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Trade secrets and know-how can be difficult to protect. We require our employees to enter into written employment agreements containing provisions of confidentiality and obligations to assign to us any inventions generated in the course of their employment. We and any third parties with whom we share facilities enter into written agreements that include confidentiality and intellectual property obligations to protect each party's potential trade secrets, proprietary know-how and information. We further seek to protect our potential trade secrets, proprietary know-how and information in part, by entering into non-disclosure and confidentiality agreements with parties who are given access to them, such as our corporate collaborators, outside scientific collaborators, contract research organizations, contract manufacturers, consultants, advisors and other third parties. With our consultants, contractors and outside scientific collaborators, these agreements typically include invention assignment obligations. We cannot guarantee that we have entered into such agreements with each party that may have or has had access to our trade secrets or proprietary technology and processes. We cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. We may need to share our proprietary information, including trade secrets, with future business partners, collaborators, contractors and others located in countries at heightened risk of theft of trade secrets, including through direct intrusion by private parties or foreign actors, and those affiliated with or controlled by state actors. Further, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third-party, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third-party, our competitive position would be harmed.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our current or future trademarks or trade names may be challenged, infringed, circumvented or declared generic or descriptive or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. During trademark registration proceedings, we may receive rejections of our applications by the USPTO or in other foreign jurisdictions. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively, and our business may be adversely affected. We may license our trademarks and trade names to third parties, such as distributors. Although these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names.

Moreover, any name we have proposed to use with our product candidates in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. Similar requirements exist in Europe. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA (or an equivalent administrative body in a foreign jurisdiction) objects to any of our proposed proprietary product names, it may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or

trademarks that incorporate variations of our registered or unregistered trademarks or trade names. If we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

Risks Related to Our Common Stock and This Offering

Our existing directors, executive officers and holders of 5% or more of our capital stock and their respective affiliates hold a substantial amount of our common stock and will be able to exert significant control over matters subject to stockholder approval.

Prior to this offering, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately % of our voting stock and, upon the closing of this offering, that same group will beneficially own approximately % of our outstanding voting stock (based on the number of shares of common stock outstanding as of June 30, 2021, assuming no exercise of the underwriters' option to purchase additional shares, no exercise of outstanding options and no purchases of shares in this offering by any of this group), in each case assuming the conversion of all outstanding shares of our convertible preferred stock into shares of our common stock immediately prior to the closing of this offering. After this offering, this group of stockholders will have the ability to control us through this ownership position even if they do not purchase any additional shares in this offering. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders. The interests of this group of stockholders may not always coincide with your interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock, and might affect the prevailing market price for our common stock.

We do not know whether a market will develop for our common stock or what the market price of our common stock will be, and, as a result, it may be difficult for you to sell your shares of our common stock.

Before this offering, there was no public trading market for our common stock. Although we expect to list our common stock on Nasdaq Global Market, an active trading market for our common stock may never develop or be sustained following this offering. If a market for our common stock does not develop or is not sustained, it may be difficult for you to sell your shares of common stock at an attractive price or at all. We cannot predict the prices at which our common stock will trade. It is possible that in one or more future periods our results of operations and progression of our product pipeline may not meet the expectations of public market analysts and investors, and, as a result of these and other factors, the price of our common stock may fall.

Our stock price may be volatile, which could result in substantial losses for investors purchasing shares in this offering.

The market price of our common stock is likely to be volatile and could fluctuate widely in response to many factors, including but not limited to:

- volatility and instability in the financial markets, capital markets due to the COVID-19 pandemic;
- announcements of the results of clinical trials by us, our collaborators or our competitors, or negative developments with respect to similar products, including those being developed by our collaborators or our competitors;
- developments with respect to patents or proprietary rights;
- announcements of technological innovations by us or our competitors;
- announcements of new products or new contracts by us or our competitors;
- actual or anticipated variations in our operating results due to the level of development expenses and other factors;
- changes in financial estimates by equities research analysts and whether our earnings meet or exceed such estimates;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders, or other stockholders;
- expiration of market standoff or lock-up agreements described under "Underwriting";

- conditions and trends in the pharmaceutical, biotechnology and other industries;
- receipt, or lack of receipt, of funding in support of conducting our business;
- regulatory developments within, and outside of, the United States, including changes in the structure of health care payment systems;
- litigation or arbitration;
- the COVID-19 pandemic, natural disasters, or major catastrophic events;
- general economic, political and market conditions and other factors; and
- the occurrence of any of the risks described in this “Risk Factors” section.

In recent years, the stock market in general, and the market for pharmaceutical and biotechnology companies in particular, has experienced significant price and volume fluctuations that have often been unrelated or disproportionate to changes in the operating performance of the companies whose stock is experiencing those price and volume fluctuations. Broad market and industry factors may seriously affect the market price of our common stock, regardless of our actual operating performance. These fluctuations may be even more pronounced in the trading market for our stock shortly following this offering.

Subject to various spending levels approved by our board of directors, our management will have broad discretion in the use of the net proceeds from our capital raises, including this offering, and may not use them effectively.

Our management will have broad discretion in the application of the net proceeds from our capital raises, including this offering, and our stockholders will not have the opportunity as part of their investment decision to assess whether the net proceeds from our capital raises are being used appropriately. We cannot specify with certainty the particular uses of the net proceeds we will receive from this offering. Because of the number and variability of factors that will determine our use of the net proceeds from our capital raises, their ultimate use may vary substantially from their currently intended use, including for any of the purposes described in “Use of Proceeds” with respect to this offering. You may not agree with our decisions, and our use of the proceeds from our capital raises may not yield any return to stockholders. Our failure to apply the net proceeds of our capital raises effectively could compromise our ability to pursue our growth strategy and we might not be able to yield a significant return, if any, on our investment of those net proceeds. Stockholders will not have the opportunity to influence our decisions on how to use our net proceeds from our capital raises. Pending their use, we may invest the net proceeds from our capital raises in interest and non-interest bearing cash accounts, short-term, investment-grade, interest-bearing instruments and U.S. government securities. These temporary investments are not likely to yield a significant return.

You will incur immediate and substantial dilution as a result of this offering.

If you purchase common stock in this offering, you will incur immediate and substantial dilution of $ per share, representing the difference between the assumed initial public offering price of $ per share, the midpoint of the price range set forth on the cover page of this prospectus, and our pro forma net tangible book value per share after giving effect to this offering and the automatic conversion of all outstanding shares of our convertible preferred stock upon the completion of this offering. Moreover, we issued options in the past that allow the holders to acquire common stock at prices significantly below the assumed initial public offering price. As of June 30, 2021, there were shares subject to outstanding options with a weighted-average exercise price of $ per share. To the extent that these outstanding options are ultimately exercised or the underwriters exercise their option to purchase additional shares, you will incur further dilution. For a further description of the dilution you will experience immediately after this offering, see “Dilution.”

You may experience future dilution as a result of future equity offerings or other equity issuances.

We will have to raise additional capital in the future. To raise additional capital, we may in the future offer additional shares of our common stock or other securities convertible into or exchangeable for our common stock at prices that may be lower than the assumed initial public offering price of $ per share, the midpoint of the price range set forth on the cover page of this prospectus. In addition, investors purchasing shares or other securities in the future could have rights superior to those of investors purchasing shares in this offering. Any such issuance could result in substantial dilution to investors purchasing shares in this offering.

A sale of a substantial number of shares of our common stock may cause the price of our common stock to decline.

Based on shares outstanding as of June 30, 2021, upon completion of this offering, we will have outstanding a total of shares of common stock. Of these shares, only shares of common stock sold in this offering, or shares if the underwriters exercise in full their option to purchase additional shares, will be freely tradable, without restriction, in the public market immediately after this offering. Each of our officers,

directors and stockholders collectively holding more than % of our outstanding common stock have entered or will enter into lock-up agreements with the underwriters that restrict their ability to sell or transfer their shares. The lock-up agreements pertaining to this offering will expire 180 days from the date of this prospectus. However, our underwriters may, in their sole discretion, permit our officers, directors and other current stockholders who are subject to lock-up agreements to sell shares prior to the expiration of the lock-up agreements. See "Underwriting." After the lock-up agreements expire, based on shares outstanding as of June 30, 2021, up to an additional shares of common stock will be eligible for sale in the public market, of which are held by our officers, directors and their affiliated entities, and will be subject to volume limitations under Rule 144 under the Securities Act of 1933, as amended, or the Securities Act. In addition, shares of our common stock that are subject to outstanding stock options as of June 30, 2021 will become eligible for sale in the public market to the extent permitted by the provisions of the applicable agreements, the lock-up agreements and Rules 144 and 701 under the Securities Act. See "Shares Eligible for Future Sale."

After this offering, the holders of an aggregate of shares of our outstanding common stock as of June 30, 2021 will have rights, subject to some conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or our stockholders. We also intend to register shares of common stock that we may issue under our equity incentive plans. Once we register these shares, they will be able to be sold freely in the public market upon issuance, subject to the 180-day lock-up period under the lock-up agreements described above and in the section titled "Underwriting."

We cannot predict what effect, if any, sales of our shares in the public market or the availability of shares for sale will have on the market price of our common stock. However, future sales of substantial amounts of our common stock in the public market, including shares issued upon exercise of outstanding options, or the perception that such sales may occur, could adversely affect the market price of our common stock.

Our board of directors will be authorized to issue and designate shares of our convertible preferred stock in additional series without stockholder approval.

Our amended and restated certificate of incorporation will authorize our board of directors, without the approval of our stockholders, to issue shares of our convertible preferred stock, subject to limitations prescribed by applicable law, rules and regulations and the provisions of our amended and restated certificate of incorporation, as shares of convertible preferred stock in series, to establish from time to time the number of shares to be included in each such series and to fix the designation, powers, preferences and rights of the shares of each such series and the qualifications, limitations or restrictions thereof. The powers, preferences and rights of these additional series of convertible preferred stock may be senior to or on parity with our common stock, which may reduce its value.

We do not anticipate paying cash dividends for the foreseeable future, and therefore investors should not buy our stock if they wish to receive cash dividends. Investors in this offering may never obtain a return on their investment.

You should not rely on an investment in our common stock to provide dividend income. We have never declared or paid any cash dividends or distributions on our common stock. We currently intend to retain our future earnings to support operations and to finance expansion and, therefore, we do not anticipate paying any cash dividends on our common stock in the foreseeable future. In addition, any future credit facility may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. Accordingly, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any return on their investment. As a result, investors seeking cash dividends should not purchase our common stock.

Provisions in our amended and restated certificate of incorporate and bylaws may prevent or frustrate attempts by our stockholders to change our management and hinder efforts to acquire a controlling interest in us, and the market price of our common stock may be lower as a result.

There are provisions in our certificate of incorporation and bylaws that may make it difficult for a third party to acquire, or attempt to acquire, control of our company, even if a change in control was considered favorable by you and other stockholders. Among other things, our certificate of incorporation and bylaws will:

- permit our board of directors to issue shares of convertible preferred stock, with any rights, preferences and privileges as they may designate, including the right to approve an acquisition or other change in our control;
- provide that the authorized number of directors may be changed only by resolution of the board of directors, subject to the rights of any holders of convertible preferred stock;

- provide that all vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide notice in writing in a timely manner, and also meet specific requirements as to the form and content of a stockholder's notice;
- not provide for cumulative voting rights (therefore allowing the holders of a plurality of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose);
- provide that special meetings of our stockholders may be called only by the board of directors, the chairman of the board of directors, our chief executive officer or president (in the absence of a chief executive officer); and
- provide that stockholders will be permitted to amend certain provisions of our bylaws only upon receiving at least two-thirds of the votes entitled to be cast by holders of all outstanding shares then entitled to vote generally in the election of directors, voting together as a single class.

These anti-takeover provisions and other provisions in our amended and restated certificate of incorporation and bylaws could make it more difficult for stockholders or potential acquirors to obtain control of our board of directors or initiate actions that are opposed by the then-current board of directors and could also delay or impede a merger, tender offer or proxy contest involving our company. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors of your choosing or cause us to take other corporate actions you desire. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

We are not subject to the provisions of Section 203 of the Delaware General Corporation Law, which could negatively affect your investment.

We elected in our certificate of incorporation to not be subject to the provisions of Section 203 of the Delaware General Corporation Law. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. A "business combination" includes a merger, asset sale or other transaction resulting in a financial benefit to the interested stockholder. An "interested stockholder" is a person who, together with affiliates and associates, owns (or, in certain cases, within three years prior, did own) 15% or more of the corporation's voting stock. This may make us more vulnerable to takeovers that are completed without the approval of our board of directors and/or without giving us the ability to prohibit or delay such takeovers as effectively.

Our amended and restated bylaws provide that the Court of Chancery of the State of Delaware and the federal district courts of the United States of America will be exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our bylaws provide that the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, another state court in Delaware or the federal district court for the District of Delaware) is the exclusive forum for the following (except for any claim as to which such court determines that there is an indispensable party not subject to the jurisdiction of such court (and the indispensable party does not consent to the personal jurisdiction of such court within 10 days following such determination), which is vested in the exclusive jurisdiction of a court or forum other than such court or for which such court does not have subject matter jurisdiction):

- any derivative action or proceeding brought on our behalf;
- any action asserting a claim of breach of fiduciary duty;
- any action asserting a claim against us arising under the Delaware General Corporation Law, our certificate of incorporation or our bylaws; and
- any action asserting a claim against us that is governed by the internal-affairs doctrine.

Our bylaws further provide that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act or any other claim for which the U.S. federal courts have exclusive jurisdiction. The enforceability of similar exclusive federal forum

provisions in other companies' organizational documents has been challenged in legal proceedings, and while the Delaware Supreme Court has ruled that this type of exclusive federal forum provision is facially valid under Delaware law, there is uncertainty as to whether other courts would enforce such provisions and that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder.

These exclusive forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. Alternatively, if a court were to find either exclusive forum provision in our certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could have a material adverse effect on our business, financial condition, and results of operations.

Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us.

Our certificate of incorporation and bylaws provide that we will indemnify our directors and officers, in each case to the fullest extent permitted by Delaware law. In addition, as permitted by Section 145 of the Delaware General Corporation Law, our bylaws and our indemnification agreements that we have entered into with our directors and officers provide that:

- We will indemnify our directors and officers for serving us in those capacities or for serving other business enterprises at our request, to the fullest extent permitted by Delaware law. Delaware law provides that a corporation may indemnify such person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the registrant and, with respect to any criminal proceeding, had no reasonable cause to believe such person's conduct was unlawful.
- We may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law.
- We are required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification.
- We are not obligated pursuant to our bylaws to indemnify a person with respect to proceedings initiated by that person against us or our other indemnitees, except with respect to proceedings authorized by our board of directors or brought to enforce a right to indemnification.
- The rights conferred in our bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons.
- We may not retroactively amend our bylaw provisions to reduce our indemnification obligations to directors, officers, employees and agents.

To the extent that a claim for indemnification is brought by any of our directors or officers, it would reduce the amount of funds available for use in our business.

General Risk Factors

We are an "emerging growth company" and a "smaller reporting company," and the reduced disclosure requirements applicable to emerging growth companies and smaller reporting companies could make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act, and may remain an "emerging growth company" for up to five years following the completion of our IPO, or December 31, 2026, although, if we have more than $1.07 billion in annual revenue, the market value of our common stock that is held by non-affiliates exceeds $700 million as of June 30th of any year, or we issue more than $1.0 billion of non-convertible debt over a three-year period before the end of that five-year period, we would cease to be an "emerging growth company" as of the following December 31st. For as long as we remain an "emerging growth company," we are

permitted and intend to continue to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not "emerging growth companies." These exemptions include:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;
- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We will take advantage of reduced reporting requirements in our public filings. In particular, we have not included all of the executive compensation related information that would be required if we were not an emerging growth company. We have elected to use this extended transition period to enable us to comply with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date we (1) are no longer an emerging growth company or (2) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our financial statements may not be comparable to companies that comply with the new or revised accounting standards as of public company effective dates.

In addition, we are also a "smaller reporting company" because the market value of our stock held by non-affiliates plus the proposed aggregate amount of gross proceeds to us as a result of this offering is less than $700 million as of June 30, 2020 and our annual revenue was less than $100 million during the fiscal year ended December 31, 2020. We may continue to be a smaller reporting company after this offering in any given year if either (i) the market value of our stock held by non-affiliates is less than $250 million as of June 30th in the most recently completed fiscal year, or (ii) our annual revenue is less than $100 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700 million as of June 30th in the most recently completed fiscal year. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

Even after we no longer qualify as an emerging growth company, we may, under certain circumstances, still qualify as a "smaller reporting company," which would allow us to take advantage of many of the same exemptions from disclosure requirements, including reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. Investors may find our common stock less attractive as a result of our reliance on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and the market price of our common stock may be reduced or more volatile.

If equities or industry analysts do not publish research or reports about our company, or if they issue adverse or misleading opinions regarding us or our stock, our stock price and trading volume could decline.

The trading market for our common stock will rely in part on the research and reports that industry or financial analysts publish about us or our business. If no or few analysts commence coverage of us or if such coverage is not maintained, the market price for our stock may be adversely affected. Our stock price also may decline if any analyst who covers us issues an adverse or erroneous opinion regarding us, our business model, our intellectual property or our stock performance, or if our clinical trials and operating results fail to meet analysts' expectations. If one or more analysts cease coverage of us or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our stock price or trading volume to decline and possibly adversely affect our ability to engage in future financings.

Failure to establish and maintain effective internal controls in accordance with Section 404 of the Sarbanes-Oxley Act could have a material adverse effect on our business and if investors lose

confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline significantly.

We are not currently required to comply with the rules of the SEC implementing Section 404 of the Sarbanes-Oxley Act and are therefore not required to make a formal assessment of the effectiveness of our internal control over financial reporting for that purpose. Upon becoming a public company, we will be required to comply with the SEC's rules implementing Sections 302 and 404 of the Sarbanes-Oxley Act, which will require management to certify financial and other information in our quarterly and annual reports and provide an annual management report on the effectiveness of controls over financial reporting. Although we will be required to disclose changes made in our internal controls and procedures on a quarterly basis, we will not be required to make our first annual assessment of our internal control over financial reporting pursuant to Section 404 until our second annual report on Form 10-K. However, as an emerging growth company, our independent registered public accounting firm will not be required to formally attest to the effectiveness of our internal control over financial reporting pursuant to Section 404 until the later of the year following our first annual report required to be filed with the SEC or the date we are no longer an emerging growth company. At such time, our independent registered public accounting firm may issue a report that is adverse in the event it is not satisfied with the level at which our controls are documented, designed or operating.

As a private company, we do not currently have any internal audit function. To comply with the requirements of being a public company, we have undertaken various actions, and will need to take additional actions, such as implementing numerous internal controls and procedures and hiring additional accounting or internal audit staff or consultants. Testing and maintaining internal control can divert our management's attention from other matters that are important to the operation of our business. Additionally, when evaluating our internal control over financial reporting, we may identify material weaknesses that we may not be able to remediate in time to meet the applicable deadline imposed upon us for compliance with the requirements of Section 404. If we identify any material weaknesses in our internal control over financial reporting or are unable to comply with the requirements of Section 404 in a timely manner or assert that our internal control over financial reporting is effective, or if our independent registered public accounting firm is unable to express an opinion as to the effectiveness of our internal control over financial reporting once we are no longer an emerging growth company, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock could be negatively affected, and we could become subject to investigations by the stock exchange on which our securities are listed, the SEC or other regulatory authorities, which could require additional financial and management resources. In addition, if we fail to remedy any material weakness, our financial statements could be inaccurate, and we could face restricted access to capital markets.

If a restatement of our financial statements were to occur, our stockholders' confidence in our financial reporting in the future may be affected, which could in turn have a material adverse effect on our business and stock price.

If any material weaknesses in our internal control over financial reporting are discovered or occur in the future, our consolidated financial statements may contain material misstatements, and we could be required to further restate our financial results. In addition, if we are unable to successfully remediate any future material weaknesses in our internal controls or if we are unable to produce accurate and timely financial statements, our stock price may be adversely affected, and we may be unable to maintain compliance with applicable stock exchange listing requirements.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

Upon the completion of this offering, we will become subject to the periodic reporting requirements of the Exchange Act. We designed our disclosure controls and procedures to provide reasonable assurance that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

Unfavorable global economic conditions could adversely affect our business, financial condition, results of operations, or prospects.

Our business, financial condition, results of operations or prospects could be adversely affected by general conditions in the global economy and in the global financial markets. A severe or prolonged economic downturn, or additional global financial crises, including those related to the COVID-19 pandemic, could result in a variety of risks to our business, including weakened demand for our product candidates, if approved, or our inability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business,

Our operations are vulnerable to business disruptions, including events beyond our control, which could seriously harm operations and financial condition and increase our costs and expenses.

Our operations could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. We rely on third-party manufacturers to produce our product candidates. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers were affected by a man-made or natural disaster or other business interruption. In addition, our corporate headquarters is located in San Diego County, California, near major earthquake faults and fire zones, and the ultimate impact on us for being located near major earthquake faults and fire zones and being consolidated in a certain geographical area is unknown. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses.

We expect to incur significant additional costs as a result of being a public company, which may adversely affect our business, financial condition, results of operations, prospects, and the price of our common stock.

Upon completion of this offering, we expect to incur costs associated with corporate governance requirements that will become applicable to us as a public company, including rules and regulations of the SEC, under the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, and the Securities Exchange Act of 1934, as amended (the Exchange Act), as well as the rules of Nasdaq. These rules and regulations are expected to significantly increase our accounting, legal, insurance, financial compliance and other costs and make some activities more time-consuming. The Exchange Act will require us to file annual, quarterly and current reports with respect to our business and financial condition within specified time periods and to prepare a proxy statement with respect to our annual meeting of stockholders. The Sarbanes-Oxley Act will require that we maintain effective disclosure controls and procedures and internal controls over financial reporting. Nasdaq will require that we comply with various corporate governance requirements. To maintain and improve the effectiveness of our disclosure controls and procedures and internal controls over financial reporting and comply with the Exchange Act and Nasdaq requirements, significant resources and management oversight will be required. This may divert management's attention from other business concerns and lead to significant costs associated with compliance, which could have a material adverse effect on us and the price of our common stock.

The expenses incurred by public companies generally for reporting and corporate governance purposes have been increasing. We expect these laws and regulations to increase our legal and financial compliance costs and to make some activities more time-consuming and costly, although we are currently unable to estimate these costs with any degree of certainty. These laws and regulations could also make it more difficult or costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. These laws and regulations could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors or its committees or as our executive officers. Advocacy efforts by stockholders and third parties may also prompt even more changes in governance and reporting requirements. We cannot predict or estimate the amount of additional costs we may incur or the timing of these costs. Furthermore, if we are unable to satisfy our obligations as a public company, we could be subject to delisting of our common stock, fines, sanctions and other regulatory action and potentially civil litigation. Accordingly, increases in costs incurred as a result of becoming a publicly traded company may adversely affect our business, financial condition, results of operations, and prospects.

We may be subject to securities litigation, which is expensive and could divert management attention.

Following periods of volatility in the market price of a company's securities, securities class action litigation has often been brought against that company. Because of the potential volatility of our stock price, we may become the target of securities litigation in the future. Securities litigation against us could result in substantial costs and divert our management's attention and resources from our business, which could seriously harm our business.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements that are based on our management's beliefs and assumptions and on information currently available to our management. Some of the statements under "Prospectus Summary," "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Business" and elsewhere in this prospectus contain forward-looking statements. In some cases, you can identify forward- looking statements by the following words: "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "ongoing," "plan," "potential," "predict," "project," "should," "will," "would" or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words.

These forward-looking statements involve risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. Although we believe that we have a reasonable basis for each forward-looking statement contained in this prospectus, we caution you that these statements are based on a combination of facts and factors currently known by us and our projections of the future, about which we cannot be certain. Forward-looking statements in this prospectus include, but are not limited to, statements about:

- our expectations regarding the potential benefits of our strategy and technology;
- our expectations regarding the operation of our product candidates and related benefits;
- our beliefs regarding the benefits and perceived limitations of competing approaches, and the future of competing technologies and our industry;
- details regarding our strategic vision and planned product candidate pipeline;
- our beliefs regarding the success, cost and timing of our product candidate development activities and current and future clinical trials and studies, including study design;
- the timing or likelihood of regulatory filings or other actions and related regulatory authority responses;
- any impact of the COVID-19 pandemic, or responses to the COVID-19 pandemic, on our business, clinical trials or personnel;
- the ability and willingness of various third parties to engage in research and development activities involving our product candidates, and our ability to leverage those activities;
- our expectations regarding the ease of administration associated with our product candidates;
- our expectations regarding the patient compatibility associated with our product candidates;
- our beliefs regarding the potential markets for our product candidates and our ability to serve those markets;
- the ability to obtain and maintain regulatory approval of any of our product candidates, and any related restrictions, limitations and/or warnings in the label of any approved product candidate;
- our ability to commercialize any approved products;
- the rate and degree of market acceptance of any approved products;
- our ability to attract and retain key personnel;
- the accuracy of our estimates regarding our future revenue, as well as our future operating expenses, capital requirements and needs for additional financing;
- our ability to obtain funding for our operations, including funding necessary to complete further development and any commercialization of our product candidates;
- our ability to obtain, maintain, protect and enforce intellectual property protection for our product candidates and technology and not infringe, misappropriate or otherwise violate the intellectual property of others;
- our expected use of the net proceeds to us from this offering;
- regulatory developments in the United States and foreign countries; and
- our expectations regarding the period during which we qualify as an "emerging growth company" under the JOBS Act, and a "smaller reporting company," as defined in Rule 12b-2 of the Exchange Act.

You should refer to the “Risk Factors” section of this prospectus for a discussion of other important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this prospectus will prove to be accurate.

In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this prospectus, and although we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted a thorough inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

MARKET, INDUSTRY AND OTHER DATA

This prospectus contains market data and industry forecasts that were obtained from industry publications. These data involve a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. We have not independently verified any third-party information. While we believe the market position, market opportunity and market size information included in this prospectus is generally reliable, such information is inherently imprecise.

This prospectus contains statistical data, estimates, and forecasts that are based on independent industry publications or reports or other publicly available information, as well as other information based on our internal sources. This information involves a number of assumptions and limitations, is subject to risks and uncertainties, and is subject to change based on various factors, including those discussed in the section titled “Risk Factors” and elsewhere in this prospectus. These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties and by us.

USE OF PROCEEDS

We estimate that the net proceeds from this offering will be approximately $ million, or approximately $ million if the underwriters exercise in full their option to purchase additional shares, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, assuming an initial offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus.

Each $1.00 increase or decrease in the assumed initial public offering price of $ per share would increase or decrease, as applicable, the aggregate net proceeds to us from this offering by approximately $ million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. We may also increase or decrease the number of shares we are offering. Similarly, each increase or decrease of 1.0 million shares in the number of shares offered by us would increase or decrease, as applicable the net proceeds to us from this offering by approximately $ million, assuming that the assumed initial public offering price remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. We do not expect that a change in the initial public offering price or the number of shares by these amounts would have a material effect on our uses of the proceeds from this offering, although it may change the time when we will need to seek additional capital.

We currently intend to use the net proceeds from this offering, together with our existing cash and cash equivalents as follows:

- approximately $ to fund the clinical development of VTX958, including through completion of ;
- approximately $ to fund the clinical development of VTX002, including through completion of ;
- approximately $ to fund the clinical development of VTX2735, including through completion of ;
- approximately $ to fund research activities and preclinical development of our other development programs; and
- any remaining proceeds, if any, for business development activities, working capital needs and other general corporate purposes.

We may also use a portion of our net proceeds to acquire, license or invest in complementary products, technologies, or businesses; however, we currently have no agreements or commitments to complete any such transactions. Since we expect to use a portion of the net proceeds from this offering for working capital and other general corporate purposes, our management will have broad discretion over the use of the net proceeds from this offering.

The net proceeds from this offering, together with our existing cash and cash equivalents, will not be sufficient for us to fund any of our product candidates through regulatory approval, and we will need to raise additional capital to achieve our business objectives. Based on current business plans, we believe that the net proceeds from this offering, together with our existing cash and cash equivalents, will be sufficient to fund our planned operations for at least the next months. For additional information regarding our potential capital requirements, see the section titled “Risk Factors.”

Pending our use of the net proceeds from this offering, we intend to invest the net proceeds in a variety of interest-bearing instruments, including short-term interest-bearing investment-grade securities, certificates of deposit or government securities.

DIVIDEND POLICY

We have never declared or paid any cash dividends on our capital stock, and we do not currently intend to pay any cash dividends on our capital stock in the foreseeable future. We currently intend to retain all available funds and any future earnings to support operations and to finance the growth and development of our business. Any future determination to pay dividends will be made at the discretion of our board of directors subject to applicable laws and will depend upon, among other factors, our results of operations, financial condition, contractual restrictions and capital requirements. Our future ability to pay cash dividends on our capital stock may be limited by any future debt instruments or preferred securities.

CAPITALIZATION

The following table sets forth our cash and cash equivalents and capitalization as of June 30, 2021, as follows:

- on an actual basis;
- on a pro forma basis to reflect (i) the automatic conversion of all outstanding shares of our convertible preferred stock as of June 30, 2021 into an aggregate of shares of our common stock immediately prior to the completion of this offering and (ii) the adoption, filing and effectiveness of our amended and restated certificate of incorporation, which will occur immediately prior to the completion of this offering; and
- on a pro forma as adjusted basis to further reflect our sale and issuance of shares of our common stock in this offering, based on the assumed initial public offering price of $, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The pro forma as adjusted information set forth in the table below is illustrative only and will be adjusted based on the actual initial public offering price and other terms of this offering determined at pricing.

You should read this information in conjunction with our audited consolidated financial statements and the related notes included elsewhere in this prospectus, as well as the section titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations.”

	AS OF JUNE 30, 2021		
	ACTUAL	PRO FORMA	PRO FORMA AS ADJUSTED[1]
	(in thousands, except share and per share amounts) (unaudited)		
Cash and cash equivalents	$ 102,788	$ —	$ —
Convertible preferred stock, $0.0001 par value per share; 300,000,811 shares authorized, 299,369,811 shares issued and outstanding, actual; no shares authorized, issued or outstanding pro forma and pro forma as adjusted	$ 173,716	$ —	$ —
Stockholders’ equity (deficit):			
Common stock, $0.0001 par value per share; 365,000,000 shares authorized, 39,484,525 shares issued, 37,838,357 outstanding, (excluding 1,646,168 subject to repurchase), actual; shares authorized, shares issued and outstanding, pro forma (unaudited); shares authorized, shares issued and outstanding, pro forma as adjusted (unaudited)	4		
Additional paid-in capital	11,401		
Accumulated other comprehensive loss	(12)		
Accumulated deficit	(87,257)		
Total stockholders’ equity (deficit)	$ (75,864)	$ —	$ —
Total capitalization	$ 97,852	$ —	$ —

(1) Each $1.00 increase or decrease in the assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase or decrease, as applicable, the amount of our pro forma as adjusted cash and cash equivalents, additional paid-in capital, total stockholders’ equity (deficit) and total capitalization by approximately $, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase or decrease of 1.0 million shares in the number of shares offered by us would increase or decrease, as applicable, the amount of our pro forma as adjusted cash and cash equivalents, additional paid-in capital, total stockholders’ equity (deficit) and total capitalization by approximately $, assuming the assumed initial public offering price remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The number of shares of our common stock to be outstanding immediately after this offering, pro forma and pro forma as adjusted in the table above, is based on shares of our common stock outstanding as of June 30, 2021 (including the automatic conversion of all of our shares of convertible preferred stock outstanding as of June 30, 2021 into an aggregate of shares of our common stock immediately prior to the completion of this offering), and excludes the following:

- shares of common stock issuable upon exercise of options to purchase shares of our common stock outstanding as of June 30, 2021, with a weighted-average exercise price of $ per share;
- shares of common stock issuable upon exercise of options to purchase shares of our common stock that were granted after June 30, 2021, with a weighted-average exercise price of $ per share;
- shares of common stock reserved for future issuance under our 2019 Equity Incentive Plan, as amended (the 2019 Plan), as of June 30, 2021, which shares will be added to the shares to be reserved under our 2021 Equity Incentive Plan (the 2021 Plan) upon its effectiveness; and
- shares of common stock reserved for future issuance under our 2021 Plan, which will become effective on the business day immediately prior to the date of effectiveness of the registration statement of which this prospectus forms a part, as well as any automatic increases in the number of shares of common stock reserved for future issuance under the 2021 Plan.

DILUTION

If you invest in our common stock in this offering, your ownership interest will be diluted immediately to the extent of the difference between the initial public offering price per share of our common stock and the pro forma as adjusted net tangible book value per share of our common stock immediately after this offering.

Our historical net tangible book value (deficit) as of June 30, 2021 was approximately $(87.3) million, or $(1.92) per share of our common stock. Our historical net tangible book value (deficit) is the amount of our total tangible assets less our total liabilities and convertible preferred stock, which is not included within our stockholders' (deficit) equity. Historical net tangible book value per share represents historical net tangible book value (deficit) divided by the number of shares of our common stock outstanding, which includes 1,646,168 shares outstanding that are subject to our right to repurchase as of such date, as of June 30, 2021.

Our pro forma net tangible book value (deficit) as of June 30, 2021 was approximately $ million, or $ per share of our common stock. Pro forma net tangible book value (deficit) represents the amount of our total tangible assets less our total liabilities, after giving effect to the conversion of all of the shares of our convertible preferred stock outstanding as of June 30, 2021 into an aggregate of shares of common stock upon the completion of this offering. Pro forma net tangible book value per share represents pro forma net tangible book value divided by the total number of shares outstanding as of June 30, 2021, after giving effect to the conversion of all outstanding shares of our convertible preferred stock into our common stock upon the completion of this offering.

After giving further effect to our sale of shares of common stock in this offering at the assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of June 30, 2021 would have been approximately $ million, or approximately $ per share. This represents an immediate increase in pro forma as adjusted net tangible book value per share of $ to our existing stockholders and an immediate dilution in pro forma as adjusted net tangible book value per share of $ to new investors purchasing common stock in this offering. Dilution per share to new investors purchasing common stock in this offering is determined by subtracting pro forma as adjusted net tangible book value per share after this offering from the assumed initial public offering price per share paid by new investors.

The following table illustrates this dilution on a per share basis:

Assumed initial public offering price per share		$
Historical net tangible book value (deficit) per share as of June 30, 2021	$ (1.92)	
Pro forma increase in net tangible book value (deficit) per share as of June 30, 2021	$	
Pro forma net tangible book value (deficit) per share as of June 30, 2021	$	
Increase in pro forma as adjusted net tangible book value per share attributable to new investors purchasing shares in this offering		
Pro forma as adjusted net tangible book value per share after this offering		
Dilution per share to new investors participating in this offering		$

Each $1.00 increase or decrease in the assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase or decrease, as applicable, the pro forma as adjusted net tangible book value as of June 30, 2021 after this offering by approximately $ million, or approximately $ per share and would decrease or increase, as applicable, the dilution to new investors purchasing common stock in this offering by approximately $ per share, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. We may also increase or decrease the number of shares we are offering. Similarly, each increase of 1.0 million shares in the number of shares offered by us would increase the amount of our pro forma as adjusted net tangible book value as of June 30, 2021 after this offering by approximately $ million, or approximately $ per share, and would decrease the dilution per share to new investors participating in this offering by approximately $, assuming no change in the assumed initial public offering price per share and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Each decrease of 1.0 million shares in the number of shares offered by us would decrease the amount of our pro forma as adjusted net tangible book value as of June 30, 2021 after this offering by approximately

$ million, or approximately $ per share, and would increase the dilution per share to new investors participating in this offering by approximately $, assuming no change in the assumed initial public offering price per share and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. The pro forma as adjusted information is illustrative only, and we will adjust this information based on the actual initial public offering price and other terms of this offering determined at pricing.

If the underwriters exercise in full their option to purchase additional shares of our common stock, the pro forma as adjusted net tangible book value per share of our common stock, as adjusted to give effect to this offering would be $ per share, and the dilution in pro forma as adjusted net tangible book value per share to new investors purchasing common stock in this offering would be $ per share.

The following table summarizes, on a pro forma as adjusted basis, as of June 30, 2021, the number of shares of common stock purchased from us on an as converted to common stock basis, the total consideration paid, or to be paid to us and the weighted-average price per share paid, or to be paid to us, by existing stockholders and by new investors in this offering at the assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, before deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

	SHARES PURCHASED		TOTAL CONSIDERATION		WEIGHTED-AVERAGE PRICE
	NUMBER	PERCENT	AMOUNT	PERCENT	PER SHARE
Existing stockholders before this offering		%	$	%	$
New investors participating in this offering					$
Total		100 %	$	100 %	

The table above assumes no exercise of the underwriters' option to purchase additional shares in this offering. If the underwriters exercise in full their option to purchase additional shares of our common stock, the existing stockholders after this offering would own % of the total number of shares of common stock outstanding following this offering, and new investors would own % of the total number of shares of common stock outstanding after this offering.

Each $1.00 increase or decrease in the assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase or decrease, as applicable, the total consideration paid by new investors by approximately $ million, assuming that the number of shares of our common stock offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase or decrease of 1.0 million shares in the number of shares of our common stock offered by us would increase or decrease, as applicable, the total consideration paid by new investors by approximately $ million, assuming the assumed initial public offering price remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The foregoing tables and calculations (other than the historical net tangible book value calculations) are based on shares of our common stock outstanding as of June 30, 2021 (including the automatic conversion of all of our shares of convertible preferred stock outstanding as of June 30, 2021 into an aggregate of shares of our common stock immediately prior to the completion of this offering), and excludes the following:

- shares of common stock issuable upon exercise of options to purchase shares of our common stock outstanding as of June 30, 2021, with a weighted-average exercise price of $ per share;
- shares of common stock issuable upon exercise of options to purchase shares of our common stock that were granted after June 30, 2021, with a weighted-average exercise price of $ per share;

- shares of common stock reserved for future issuance under the 2019 Plan, as of June 30, 2021, which shares will be added to the shares to be reserved under our 2021 Plan upon its effectiveness; and
- shares of common stock reserved for future issuance under our 2021 Plan, which will become effective on the business day immediately prior to the date of effectiveness of the registration statement of which this prospectus forms a part, as well as any automatic increases in the number of shares of common stock reserved for future issuance under the 2021 Plan.

SELECTED CONSOLIDATED FINANCIAL DATA

The following tables set forth our selected financial data as of, and for the periods ended on, the dates indicated. We have derived the statements of operations and comprehensive loss data for the years ended December 31, 2019 and 2020 and the balance sheet data as of December 31, 2019 and 2020 from our audited financial statements included elsewhere in this prospectus. We have derived the consolidated statements of operations and comprehensive loss data for the six months ended June 30, 2020 and 2021 and the consolidated balance sheet data as of June 30, 2021 from our unaudited consolidated financial statements included elsewhere in this prospectus. The unaudited consolidated financial statements have been prepared on a basis consistent with our audited financial statements included in this prospectus and, in the opinion of management, reflect all adjustments, consisting only of normal recurring adjustments, necessary to fairly state our financial position as of June 30, 2021 and results of operations for the six months ended June 30, 2020 and 2021. You should read the following selected financial data together with our consolidated financial statements and the related notes included elsewhere in this prospectus and the section in this prospectus titled "Management's Discussion and Analysis of Financial Condition and Results of Operations." Our historical results are not necessarily indicative of results that should be expected in any future period.

	YEAR ENDED DECEMBER 31,		SIX MONTHS ENDED JUNE 30,	
	2019	2020	2020	2021
			(unaudited)	
	(in thousands, except share and per share data)			
Consolidated Statements of Operations and Comprehensive Loss Data:				
Operating expenses:				
Research and development (includes related party amounts of $1,374, $965 $647 and $462, respectively)	$ 3,552	$ 6,366	$ 3,069	$ 34,112
General and administrative (includes related party amounts of $296, $400, $221 and $116, respectively)	628	684	305	2,422
Total operating expenses	4,180	7,050	3,374	36,534
Loss from operations	(4,180)	(7,050)	(3,374)	(36,534)
Other expense:				
Other expense	1	1	—	44
Interest expense - related party	146	358	111	99
Change in fair value of notes and derivative - related party	—	20,765	831	11,051
Change in fair value of Series A tranche liability	—	—	—	5,476
Total other expense	147	21,124	942	16,670
Net loss	$ (4,327)	$ (28,174)	$ (4,316)	$ (53,204)
Deemed dividend	—	—	—	(1,552)
Net loss attributable to common stockholders	$ (4,327)	$ (28,174)	$ (4,316)	(54,756)
Net loss	$ (4,327)	$ (28,174)	$ (4,316)	$ (53,204)
Foreign currency translation	—	—	—	12
Comprehensive loss	$ (4,327)	$ (28,174)	$ (4,316)	$ (53,216)
Net loss per share attributable to common stockholders, basic and diluted (1)	$ (0.27)	$ (1.48)	$ (0.23)	$ (1.80)
Shares used to compute basic and diluted net loss per common share (1)	15,897,424	19,022,848	18,721,146	29,607,406

(1) See Note 2 to our consolidated financial statements included elsewhere in this prospectus for details on the calculation of our basic and diluted net loss per common share.

	AS OF DECEMBER 31,		AS OF JUNE 30,
	2019	2020	2021
			(unaudited)
		(in thousands)	
Consolidated Balance Sheet Data:			
Cash and cash equivalents	$ 309	$ 244	$ 102,788
Working capital (deficit) (1)	(282)	(1,158)	96,964
Total assets	349	245	105,916
Change of control derivative liability - related party	—	16,849	—
Convertible promissory notes - related party	3,846	2,920	—
Convertible SAFE notes at fair value - related party	—	9,727	—
Series A convertible preferred shares	—	—	116,279
Series A-1 convertible preferred shares	—	—	57,437
Accumulated deficit	(4,327)	(32,501)	(87,257)
Total stockholders' deficit	(4,128)	(30,654)	(75,864)

(1) Working capital is defined as current assets less current liabilities. See our consolidated financial statements and the related notes included elsewhere in this prospectus for further details regarding our current assets and current liabilities.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with the section of this prospectus titled "Selected Financial Data" and our consolidated financial statements and related notes included elsewhere in this prospectus. Some of the information contained in this discussion and analysis are set forth elsewhere in this prospectus, including information with respect to our plans and strategy for our business and related financing, and includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the section of this prospectus titled "Risk Factors," our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a clinical-stage biopharmaceutical company developing a pipeline of small molecule product candidates to address a range of inflammatory diseases with significant unmet medical need. We leverage the substantial experience of our team in immunology to identify important new targets and to develop differentiated therapeutics against these targets. Our clinical product candidates address therapeutic indications with established multi-billion-dollar potential and substantial commercial opportunity for novel first-in-class or best-in-class molecules. Our lead clinical product candidate VTX958 is a highly specific and potent Tyrosine kinase type 2 (TYK2) inhibitor which is currently in a Phase1 single ascending dose trial projected to complete in the second half of 2021. We expect to commence a Phase 1b multiple ascending dose study in the second half of 2021 and intend to initiate Phase 2 trials in psoriasis and Crohn's disease, among other potential indications. In addition, we are developing VTX002, a Phase 2-ready Sphingosine 1 phosphate receptor (S1P1R) modulator for UC, with Phase 2 trials expected to initiate in the second half of 2021. Our third product candidate, VTX2735, a peripheral-targeted NOD-like receptor protein 3 (NLRP3) inflammasome inhibitor, is expected to enter the clinic in the second half of 2021 and we are also developing CNS-penetrant and tissue-selective NLRP3 inhibitors that are currently in preclinical testing.

We were incorporated in November 2018. To date, we have focused primarily on organizing and staffing our company, business planning, raising capital, and identifying our product candidates and conducting preclinical studies and clinical trials. We have funded our operations primarily through debt and equity financings. We do not have any products approved for sale and have not generated any revenue from product sales. We have raised approximately $9.5 million from February 2019 through January 2021 through issuing convertible notes (Convertible Notes) and Simple Agreements for Future Equity (the SAFEs). In addition, in February 2021 and June 21, 2021, we raised an aggregate of $114.3 million in cash in connection with the sale of our Series A preferred stock. As of June 30, 2021, we had $102.8 million in cash and cash equivalents.

In connection with our Series A preferred stock financing, in February 2021, we acquired all of the outstanding equity and convertible debt interests of Oppilan and Zomagen (the Acquisitions) as follows:

- Pursuant to the terms of the Share Purchase Agreement (the Oppilan Purchase Agreement), we issued to the shareholders of Oppilan 3,451,419 shares of our common stock, 38,727,626 shares of our Series A-1 convertible preferred stock and options to purchase 726,546 shares of our common stock in exchange for all of the outstanding equity interests of Oppilan. Oppilan's lead candidate, VTX002, is a modulator of the S1P receptor that has a unique pharmacokinetic and pharmacodynamic profile, and recently completed phase 1 clinical testing.
- Pursuant to the terms of the Share Purchase Agreement (the Zomagen Purchase Agreement), we issued to the shareholders of Zomagen 4,380,030 shares of our common stock, 19,164,836 shares of our Series A-1 convertible preferred stock and options to purchase 291,577 shares of our common stock in exchange for all of the outstanding equity interests of Zomagen. Zomagen's lead candidate, VTX2735, is a pre-clinical stage program focused on high value targets of the NLRP3 inflammasome, targeting chronic inflammatory disorders.

The fair value of total cost of the Acquisitions was $14.1 million and $7.8 million for Oppilan and Zomagen, respectively. The excess of the cost of acquisition over net assets acquired was $12.9 million and $8.9 million for Oppilan and Zomagen, respectively. We determined that there is no alternative future use of the in-process research and development (IPR&D) assets acquired from either acquisition and, accordingly, the excess of the cost of acquisition over net assets acquired was expensed as IPR&D at the respective acquisition date. For the

six months ended June 30, 2021, we recorded the excess IPR&D costs of $21.8 million in research and development costs within our consolidated statements of operations and comprehensive loss.

We have incurred significant operating losses since our inception and expect to continue to incur significant operating losses for the foreseeable future. For the years ended December 31, 2019 and 2020, and for the six months ended June 30, 2020 and 2021, our net loss was $4.3 million, $28.2 million, $4.3 million, and $53.2 million, respectively. As of June 30, 2021, we had an accumulated deficit of $87.3 million. We expect our expenses and operating losses will increase substantially as we conduct our ongoing and planned clinical trials, continue our research and development activities and conduct preclinical studies, and seek regulatory approvals for our product candidates, as well as hire additional personnel, protect our intellectual property and incur additional costs associated with being a public company. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on a variety of factors including the timing and scope of our preclinical and clinical studies and our expenditures on other research and development activities.

We do not expect to generate any revenue from product sales unless and until we successfully complete clinical development and obtain regulatory approval for one or more of our product candidates, which we expect will take at least a number of years. If we do obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. Accordingly, until such time as we can generate substantial product revenues to support our cost structure, if ever, we expect to finance our cash needs through equity offerings, debt financings or other capital sources, including potentially collaborations, licenses and other similar arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our failure to raise capital or enter into such other arrangements when needed could have a negative impact on our financial condition and on our ability to pursue our business plans and strategies. If we are unable to raise additional capital when needed, we could be forced to delay, limit, reduce or terminate our product candidate development or future commercialization efforts or grant rights to develop and market our product candidates even if we would otherwise prefer to develop and market such product candidates ourselves.

The global COVID-19 pandemic continues to rapidly evolve. The extent of the impact of the COVID-19 on our business, operations and clinical development timelines and plans remains uncertain, and will depend on certain developments, including the duration and spread of the outbreak and its impact on our operations and those of our CROs, third-party manufacturers, and other third parties with whom we do business, as well as its potential impact on regulatory authorities and our ability to attract and retain key scientific and management personnel. The ultimate impact of the COVID-19 pandemic or a similar health epidemic is highly uncertain and subject to change. To the extent possible, we are conducting business as usual, with necessary or advisable modifications to employee travel and most of our office employees working remotely. We will continue to actively monitor the rapidly evolving situation related to COVID-19 and may take further actions that alter our operations, including those that may be required by federal, state or local authorities, or that we determine are in the best interests of our employees and other third parties with whom we do business. At this point, the extent to which the COVID-19 pandemic may affect our business, operations and clinical development timelines and plans, including the resulting impact on our expenditures and capital needs, remains uncertain and is subject to change.

Support Services Agreement with Kalika Biosciences, Inc.

On January 1, 2019, we entered into a Support Services Agreement, (the Kalika Services Agreement) with Kalika, that outlines the terms of services provided by Kalika, as well as the fees we are charged for such services. Kalika is a shared service company that provides certain administrative and research and development support services, including facilities support. Kalika is beneficially owned by Raju Mohan, PhD., our chief executive officer, and NSV Management LLC, which is affiliated with both a non-employee director and certain funds of New Science Ventures, which are also, collectively, beneficial owners of more than 5% of our capital stock. We pay Kalika monthly for costs incurred under the Kalika Services Agreement. Either party may terminate the Kalika Services Agreement by giving 30 days' prior notice. On March 1, 2021, in conjunction with the acquisitions of Oppilan and Zomagen, we terminated the Kalika Services Agreement with Kalika and transitioned substantially all of the employees of Kalika to our company.

Research and Development Support Services Agreement with Bayside Pharma, LLC

On October 17, 2019, we entered into a Research and Development Support Services Agreement, (the Bayside Agreement) with Bayside Pharma, LLC, (Bayside), that outlines the terms of services provided by Bayside, as well as the fees we are charged for such services. Bayside is a research and development services company that provides certain research and development support services and facilities. Bayside is owned by one of our non-executive employees. We pay Bayside monthly for costs incurred under the Bayside Agreement. Either party may terminate the Bayside Agreement by giving 30 days' prior notice.

Financial Operations Overview

Revenues

We have not generated any revenue since our inception and do not expect to generate any revenue from the sale of products for the foreseeable future. We may also generate revenues in the future from payments or royalties associated with potential partnering or collaboration agreements, but have no plans to enter into such arrangements at this time.

Research and Development Expenses

Research and development expense consists of expenses incurred while performing research and development activities to discover and develop our product candidates. Research and development costs include salaries, payroll taxes, employee benefits, and stock-based compensation charges for those individuals involved in our ongoing research and development efforts; as well as fees paid to consultants and third party research organizations, and the costs of laboratory supplies and development compound materials. Costs incurred in our research and development efforts are expensed as incurred.

We typically use our employee, consultant and infrastructure resources across our research and development programs. We track outsourced development costs by product candidate or development program, but we do not allocate personnel costs, other internal costs or external consultant costs to specific product candidates or development programs.

Substantially all of our research and development expenses to date have been incurred in connection with the discovery and development of our product candidates. We expect our research and development expenses to increase significantly for the foreseeable future as we advance an increased number of our product candidates through clinical development, including the conduct of our ongoing and planned clinical trials. The process of conducting clinical trials necessary to obtain regulatory approval is costly and time consuming. The successful development of product candidates is highly uncertain and subject to numerous risks and uncertainties. Accordingly, at this time, we cannot reasonably estimate the nature, timing or costs required to complete the remaining development of any product candidates and to obtain regulatory approval for one or more of these product candidates.

The costs of clinical trials may vary significantly over the life of a project owing to, but not limited to, the following:

- per patient trial costs;
- the number of sites included in the clinical trials;
- the countries in which the clinical trials are conducted;
- the length of time required to enroll eligible patients;
- the number of patients that participate in the clinical trials and the drop-out or discontinuation rates of such patients;
- the number of doses that patients receive;
- the cost of comparative agents used in clinical trials;
- potential additional safety monitoring or other studies requested by regulatory agencies;
- the duration of patient follow-up; and
- the efficacy and safety profile of the product candidate.

We do not expect any of our product candidates to be commercially available for at least the next several years, if ever.

General and Administrative Expenses

General and administrative expense is related to finance, human resources, legal and our other administrative activities. These expenses consist primarily of personnel costs, including stock-based compensation expenses, outside services, legal expenses, management fees and other general and administrative costs.

We expect that our general and administrative expenses will increase for the foreseeable future as we expand operations, increase our headcount to support our continued research and development activities and operate as a public reporting company (including increased fees for outside consultants, lawyers and accountants, as well as increased directors' and officers' liability insurance premiums). We also expect to incur increased costs to comply with stock exchange listing and SEC requirements, corporate governance, internal controls, investor relations and disclosure and similar requirements applicable to public companies. Additionally, if and when we believe that a regulatory approval of a product candidate appears likely, we expect to incur significant increases in our general and administrative expenses relating to the sales and marketing of any approved product candidate.

Interest Expense – Related Parties

Interest expense consists of interest on our Convertible Notes that converted in February 2021.

Increase in Fair Value of Change of Control Derivative Liability – Related Parties

We issued the Convertible Notes in 2019 and 2020. The convertible promissory notes included a change of control feature for which we have recorded a liability measured at fair value. Until their conversion into Series A-1 convertible preferred stock in February 2021, we adjusted the carrying value of our change in control feature to its estimated fair value at each reporting date, with the increases in fair value of the change of control feature recorded in our consolidated statements of operations and comprehensive loss.

We estimated the fair value of our change of control feature using a combination of probability analysis and Monte Carlo simulation methodology. Probabilities are used to establish a distribution of time to a financing or change of control and Monte Carlo simulation is used to forecast future equity values at the time of either event, which then are used to estimate the future values of the notes upon either event. The key inputs to the Monte Carlo simulation include inputs including the common stock price, volatility of common stock, the risk-free interest rate and the probability of conversion into common shares at the conversion rate in the event of a change in control or major transaction (e.g., liquidity). Fair value measurements are highly sensitive to changes in these inputs and significant changes could result in a significantly higher or lower fair value and resulting expense or gain.

Increase in Fair Value of Convertible SAFE Notes – Related Parties

We issued SAFEs in 2019 and 2020 for which we have elected to account for at fair value. Until their conversion into Series A-1 convertible preferred stock in February 2021, we adjusted the carrying value of our SAFEs to their estimated fair value at each reporting date, with the increases in fair value of the SAFEs recorded in our consolidated statements of operations and comprehensive loss.

We estimated the fair value of our SAFEs using a combination of probability analysis and Monte Carlo simulation methodology. Probabilities are used to establish a distribution of time to a financing or change of control and Monte Carlo simulation is used to forecast future equity values at the time of either event, which then are used to estimate the future values of the notes upon conversion or payout upon either event. The key inputs to the Monte Carlo simulation include inputs including the common stock price, volatility of common stock, the risk-free interest rate and the probability of conversion into common shares at the conversion rate in the event of a change in control or major transaction (e.g., liquidity). The SAFEs were initially recorded at an amount equal to the value of consideration received.

Increase in Fair Value of Series A Tranche Liability – Related Parties

On February 26, 2021, we issued 60,097,042 shares of our Series A convertible preferred stock for gross proceeds of $57.3 million at the original issue price of $0.9534578 per share. The Series A purchase agreement allowed the original investors to purchase an additional 59,782,399 shares of Series A Convertible Preferred Shares (the "Additional Shares"), on the same terms and conditions as the original issuance at the original issue price of $0.9534578 per share (the "Second Closing" or "Tranche Liability"). In addition, we were obligated to issue 4,850,428 shares of common stock to a Series A investor if they participate in the second tranche. We concluded that these rights or obligations of the investors to participate in the second tranche of the Series A convertible preferred stock meet the definition of a freestanding instrument that was required to be recorded as a liability at fair value (Series A tranche liability). Given the common shares were linked to the second tranche, they were also considered a component of the Tranche Liability. On June 10, 2021, the

investors purchased an additional 59,782,399 shares of our Series A convertible preferred stock, on the same terms and conditions as the original issuance for gross proceeds of $57.0 million in a second closing. Until the conversion of Series A tranche liability into Series A convertible preferred stock on June 10, 2021, we adjusted the carrying value of our Series A tranche liability to its estimated fair value at each reporting date, with the increases in fair value of the Series A tranche liability recorded as increase in fair value of Series A tranche liability in our consolidated statements of operations and comprehensive loss.

We estimated the fair value of the Series A tranche liability using a combination of probability analysis and Monte Carlo simulation methodology. Probabilities are used to establish a distribution of time to a financing or change of control and Monte Carlo simulation is used to forecast future equity values at the time of either event, which then are used to estimate the future values of the notes upon conversion or payout upon either event. The key inputs to the Monte Carlo simulation include inputs including the common stock price, volatility of common stock, the risk-free interest rate and the probability of conversion into common shares at the conversion rate in the event of a change in control or major transaction (e.g., liquidity).

Results of Operations

The presentation of our consolidated financial statements for the six months ended June 30, 2021, reflect the financial results of Ventyx Biosciences, Inc., and the financial results of our two acquired subsidiaries, Oppilan and Zomagen, from the acquisition date to June 30, 2021, on a consolidated basis.

Comparison of the Six Months Ended June 30, 2020 and 2021

The following table summarizes our consolidated results of operations for the six months ended June 30, 2020 and 2021:

	SIX MONTHS ENDED June 30,		
	2020	2021	CHANGE
	(unaudited) (in thousands)		
Operating expenses:			
Research and development (includes related party amounts of $647 and $462, respectively)	$ 3,069	$ 34,112	$ 31,043
General and administrative (includes related party amounts of $221 and $116, respectively)	305	2,422	2,117
Total operating expenses	3,374	36,534	33,160
Loss from operations	(3,374)	(36,534)	(33,160)
Other expense:			
Other expense	—	44	44
Interest expense - related party	111	99	(12)
Change in fair value of notes and derivative - related party	831	11,051	10,220
Change in fair value of Series A tranche liability	—	5,476	5,476
Total other expense	942	16,670	15,728
Net loss	$ (4,316)	$ (53,204)	$ (48,888)
Deemed dividend	—	$ (1,552)	(1,552)
Net loss attributable to common shareholders	$ (4,316)	$ (54,756)	$ (50,440)
Net Loss	$ (4,316)	$ (53,204)	$ (48,888)
Foreign currency translation	—	(12)	(12)
Comprehensive loss	$ (4,316)	$ (53,216)	$ (48,900)

Research and Development Expense

Research and development expenses were $3.1 million and $34.1 million for the six months ended June 30, 2020 and 2021, respectively. The increase of $31.0 million was due to $21.8 million of IPR&D expenses associated with the acquisition of Oppilan and Zomagen, and increases in Phase 1 clinical studies for VTX958 of $1.8 million, preclinical costs of $1.6 million, compensation related expenses of $0.9 million, consultant fees

of $0.3 million, and stock-based compensation expense of $0.2 million. The remaining increase is attributable to increased expenses from the operations of Oppilan and Zomagen following their acquisition.

For the periods ended June 30, 2020 and June 30, 2021, the majority of research and development expense has been related to the development of VTX002 and VTX958.

We expect to substantially increase our research and development expenses in the future as we advance our product candidates through clinical trials and seek to advance our preclinical product candidates into clinical study.

General and Administrative Expense

General and administrative expenses were $0.3 million and $2.4 million for the six months ended June 30, 2020 and 2021, respectively. The increase of $2.1 million was due primarily to $1.8 million in stock-based compensation expense, $0.7 million in professional services, and $0.7 million in compensation related expenses. The remaining increase is attributable to increased expenses from the operations of Oppilan and Zomagen following their acquisition.

Other Expense

Other expenses were $0.9 million and $16.7 million for the six months ended June 30, 2020 and 2021, respectively. The increase of $15.7 million was due primarily to the change in the fair value of the related party notes and the derivative of $10.2 million and the change in the Series A tranche liability of $5.5 million.

Comparison of the Years Ended December 31, 2019 and 2020

The following table summarizes our results of operations for the years ended December 31, 2019 and 2020:

	YEAR ENDED DECEMBER 31,		
	2019	2020	CHANGE
	(in thousands)		
Operating expenses:			
Research and development (includes related party amounts of $1,374 and $965, respectively)	$ 3,552	$ 6,366	$ 2,814
General and administrative (includes related party amounts of $296 and $400, respectively)	628	684	$ 56
Total operating expenses	4,180	7,050	2,870
Loss from operations	(4,180)	(7,050)	(2,870)
Other expense:			
Other expense	1	1	—
Interest expense - related party	146	358	212
Change in fair value of notes and derivative - related party	—	20,765	20,765
Total other expense	147	21,124	20,977
Net loss	$ (4,327)	$ (28,174)	$ (23,847)
Foreign currency translation	—	—	—
Comprehensive loss	$ (4,327)	$ (28,174)	$ (23,847)

Research and Development Expense

Research and development expenses were $3.6 million and $6.4 million for the years ended December 31, 2019 and 2020, respectively. The increase of $2.8 million was due primarily to an increase in preclinical costs of $4.4 million and an increase in amounts incurred related to consultant fees of $0.4 million. These increases were offset by a decrease in amounts incurred related to discovery costs of $1.4 million.

General and Administrative Expense

General and administrative expenses were $0.6 million and $0.7 million for the years ended December 31, 2019 and 2020, respectively. The increase of $0.1 million was due primarily to an increase in professional service fees related.

Other Expense

Other expenses were $0.1 million and $21.1 million for the years ended December 31, 2019 and 2020, respectively. The increase of $21.0 million was due primarily to the change in fair value of related party notes and the associated derivative – related party of $20.1 million.

Liquidity and Capital Resources

Sources of Liquidity

From inception through June 30, 2021, we have funded our operations primarily through the issuance of $113.9 million of convertible preferred stock, net of offering costs, to outside investors and related parties and $10.3 million in aggregate principal amount of convertible notes and SAFEs issued to related parties.

As of December 31, 2020, we had cash and cash equivalents of $0.2 million, compared to $0.3 million as of December 31, 2019. As of June 30, 2021, we had cash and cash equivalents of $102.8 million.

Future Funding Requirements

To date, we have generated no revenue and do not expect to generate revenue unless and until we obtain regulatory approval of and commercialize any of our product candidates and we do not know when, or if, this will occur. In addition, we expect our expenses to significantly increase in connection with our ongoing development activities, particularly as we continue the research, development and clinical trials of, and seek regulatory approval for, our product candidates. Moreover, following the completion of this offering, we expect to incur additional costs associated with operating as a public company. In addition, subject to obtaining regulatory approval of our product candidates, we expect to incur significant commercialization expenses for product sales, marketing, manufacturing and distribution. We anticipate that we will need substantial additional funding in connection with our continuing operations. We expect that our expenses will increase substantially if and as we:

- continue research and development, including preclinical and clinical development of our existing product candidates;
- potentially seek regulatory approval for our product candidates;
- seek to discover and develop additional product candidates;
- establish a commercialization infrastructure and scale up our manufacturing and distribution capabilities to commercialize any of our product candidates for which we may obtain regulatory approval;
- seek to comply with regulatory standards and laws;
- maintain, leverage and expand our intellectual property portfolio;
- hire clinical, manufacturing, scientific and other personnel to support our product candidates;
- development and future commercialization efforts;
- add operational, financial and management information systems and personnel; and
- incur additional legal, accounting and other expenses in operating as a public company.

Based upon our current operating plan, we expect that the net proceeds from this offering, together with our existing cash and cash equivalents, will enable us to fund our operating expenses and capital expenditures requirements for at least the next 12 months. We have based this estimate on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect. The successful development of any product candidate is highly uncertain. Due to the numerous risks and uncertainties associated with the development and commercialization of our product candidates, if approved, we are unable to estimate the amounts of increased capital outlays and operating expenses associated with completing the development of our product candidates.

Our future capital requirements will depend on many factors, including:

- the timing of, and the costs involved in, preclinical and clinical development and obtaining any regulatory approvals for our product candidates;
- the costs of manufacturing, distributing and processing our product candidates;
- the number and characteristics of any other product candidates we develop or acquire;
- our relative responsibility for developing and commercializing product candidates covered by our collaboration agreements;
- the degree and rate of market acceptance of any approved products;
- the emergence, approval, availability, perceived advantages, relative cost, relative safety and relative efficacy of other products or treatments;
- the expenses needed to attract and retain skilled personnel;

- the costs associated with being a public company;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing intellectual property claims, including litigation costs and the outcome of such litigation;
- the timing, receipt and amount of sales of, or royalties on, any approved products; and
- any product liability or other lawsuits related to our product candidates.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity, equity-linked and debt financings, collaborations, strategic alliances and/or licensing arrangements. We do not have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities many include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or licensing arrangements with pharmaceutical partners, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates, or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market our product candidates that we would otherwise prefer to develop and market ourselves.

Cash Flows

We have incurred net losses and negative cash flows from operations since our inception and anticipate we will continue to incur net losses for the foreseeable future. As of June 30, 2021, we had cash and cash equivalents of $102.8 million.

The following table sets forth a summary of the net cash flow activity for each of the periods indicated:

	YEAR ENDED DECEMBER 31,		SIX MONTHS ENDED JUNE 30,	
	2019	2020	2020	2021
			(unaudited)	
	(In thousands)			
Net cash provided by (used in):				
Operating activities	$ (2,642)	$ (6,195)	$ (2,425)	$ (12,934)
Investing activities	—	—	—	1,888
Financing activities	2,951	6,130	2,150	113,590
Net increase (decrease) in cash and cash equivalents	$ 309	$ (65)	$ (275)	$ 102,544

Operating Activities

Net cash used in operating activities was $2.4 million and $12.9 million for the six months ended June 30, 2020 and 2021, respectively. The net cash used in operating activities for the six months ended June 30, 2020 was primarily due to our net loss of $4.3 million, partially offset by a $0.8 million noncash change in the fair value of related party notes, $0.1 million of noncash related party interest charges, and a $0.9 million change in operating assets and liabilities. The net cash used in operating activities for the six months ended June 30, 2021 was primarily due to our net loss of $53.2 million, partially offset by a $21.8 million noncash acquired in-process research and development expenses, $11.1 million noncash change in the fair value of related party notes, $5.5 million noncash change in the fair value of the Series A tranche liability, $0.4 million of noncash stock-based compensation expense, and a $1.5 million change in operating assets and liabilities primarily related to a decrease in prepaid expenses and other assets of $1.7 million and an increase in accrued expenses of $3.1 million.

Net cash used in operating activities was $2.6 million and $6.2 million for the years ended December 31, 2019 and 2020, respectively. The net cash used in operating activities for the year ended December 31, 2019 was primarily due to our net loss of $4.3 million, partially offset by $0.8 million related to the noncash exchange of notes with a related party for acquired intellectual property, $0.1 million of noncash related party interest charges, $0.2 million of noncash stock-based compensation expense, and a $0.6 million change in operating

assets and liabilities. The net cash used in operating activities for the year ended December 31, 2020 was primarily due to our net loss of $28.2 million, partially offset by a $20.8 million noncash change in the fair value of related party notes, and a $0.8 million change in operating assets and liabilities.

Investing Activities

Net cash provided by investing activities was $1.9 million for the six months ended June 30, 2021 related to $1.9 million of net cash assumed in connection with the acquisition of Oppilan and Zomagen. We had no cash flows from investing activities for the years ended December 31, 2020 and 2021, and the six months ended June 30, 2020.

Financing Activities

Net cash provided by financing activities of $2.2 million for the six months ended June 30, 2020 are attributable to the net proceeds received from the issuance of SAFEs. Net cash provided by financing activities of $113.6 million for the six months ended June 30, 2021, included $113.5 million of proceeds from the issuance of our Series A convertible preferred stock net of offering costs and $0.5 million of net proceeds from the issuance of SAFEs, offset by $0.3 million of cash paid for deferred offering costs.

Net cash provided by financing activities of $3.0 million for the year ended December 31, 2019 reflected the net proceeds from the issuance of Convertible Notes. Net cash provided by financing activities of $6.1 million for the year ended December 31, 2020 reflected the net proceeds from the issuance of SAFEs.

Contractual Obligations and Commitments

We enter into contracts in the normal course of business with third-party contract organizations and vendors for preclinical studies, manufacturing, research supplies and other services and products for operating purposes. These contracts generally provide for termination after a notice period, and, therefore, are cancelable contracts not required to be included in a contractual obligations table.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles (GAAP). The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, and expenses and the disclosure of contingent assets and liabilities in our consolidated financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to accruals for research and development expenses, stock-based compensation and fair value measurements. We base our estimates on historical experience, known trends and events, and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in Note 2 to our consolidated financial statements included elsewhere in this prospectus, we believe the following accounting policies and estimates to be most critical to the preparation of our consolidated financial statements.

Acquisitions

We account for acquisitions of an asset or group of similar identifiable assets that do not meet the definition of a business as asset acquisitions. Intangible assets acquired in an asset acquisition for use in research and development activities which have no alternative future use are expensed as in-process research and development (IPR&D) on the acquisition date. In connection with the acquisitions of Oppilan and Zomagen as described above, we considered the accounting treatment for the acquisitions in accordance with GAAP. We apply judgment when concluding if our acquisitions meet the definition of a business in accordance with GAAP and substantially all of the fair value of the gross assets acquired are concentrated in a group of similar assets. We determined that substantially all of the fair value of the net assets acquired of Oppilan and Zomagen were concentrated in a group of similar assets. As a result, the transactions were accounted for as an asset acquisition and as such, no goodwill was recorded. The excess of the cost of the acquisitions over the net assets acquired was classified as IPR&D assets and expensed at the acquisition date as we determined there was no alternative future use.

Accrued Research and Development Expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued expenses as of each consolidated balance sheet date. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. We make estimates of our accrued expenses as of each consolidated balance sheet date based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments, if necessary. The significant estimates in our accrued research and development expenses include the costs incurred for services performed by our vendors in connection with research and development activities for which we have not yet been invoiced.

We base our expenses related to research and development activities on our estimates of the services received and efforts expended pursuant to quotes and contracts with vendors that conduct research and development on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the research and development expense. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or prepaid expense accordingly. Advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made.

Although we do not expect our estimates to be materially different from amounts actually incurred, if our estimates of the status and timing of services performed differ from the actual status and timing of services performed, it could result in us reporting amounts that are too high or too low in any particular period. To date, there have been no material differences between our estimates of such expenses and the amounts actually incurred.

Stock-Based Compensation Expense

Stock-based compensation expense represents the cost of the grant date fair value of equity awards recognized over the requisite service period of the awards (usually the vesting period) on a straight-line basis. We estimate the fair value of equity awards using the Black-Scholes option pricing model and recognize forfeitures as they occur. Estimating the fair value of equity awards as of the grant date using valuation models, such as the Black-Scholes option pricing model, is affected by assumptions regarding a number of variables, including the risk-free interest rate, the expected stock price volatility, the expected term of stock options, the expected dividend yield and the fair value of the underlying common stock on the date of grant. Changes in the assumptions can materially affect the fair value and ultimately how much stock-based compensation expense is recognized. These inputs are subjective and generally require significant analysis and judgment to develop. See Note 9 to our consolidated financial statements included elsewhere in this prospectus for information concerning certain of the specific assumptions we used in applying the Black-Scholes option pricing model to determine the estimated fair value of our stock options granted, if any, during 2019 and 2020 and the six months ended June 30, 2020 and 2021. As of June 30, 2021, the unrecognized stock-based compensation expense related to stock options was $2.9 million and is expected to be recognized as expense over a weighted average period of approximately 3.0 years. The intrinsic value of all outstanding stock options as of June 30, 2021 was approximately $ million, based on the assumed offering price of $ per share (the midpoint of the price range set forth on the cover page of this prospectus), of which approximately $ million related to vested options and approximately $ million related to unvested options.

Common stock valuations

We are required to estimate the fair value of the common stock underlying our equity awards when performing fair value calculations. The fair value of the common stock underlying our equity awards was determined on the grant date by our board of directors. All options to purchase shares of our common stock are intended to be granted with an exercise price per share no less than the fair value per share of our common stock underlying those options on the date of grant, based on the information known to us on the date of grant. In the absence of a public trading market for our common stock, on each grant date we develop an estimate of the fair value of our common stock in order to determine an exercise price for the option grants.

Our board of directors considered various objective and subjective factors, along with input from management, to determine the fair value of our common stock, including:

- valuations of our common stock performed with the assistance of independent third-party valuation specialists;
- our stage of development and business strategy, including the status of research and development efforts of our platforms, programs and product candidates, and the material risks related to our business and industry;
- our results of operations and financial position, including our levels of available capital resources;
- the valuation of publicly traded companies in the life sciences and biotechnology sectors, as well as recently completed mergers and acquisitions of peer companies;
- the lack of marketability of our common stock as a private company;
- the prices of our convertible preferred stock sold to investors in arm's length transactions and the rights, preferences, and privileges of our convertible preferred stock relative to those of our common stock;
- the likelihood of achieving a liquidity event for the holders of our common stock, such as an initial public offering or a sale of our company, given prevailing market conditions;
- trends and developments in our industry; and
- external market conditions affecting the life sciences and biotechnology industry sectors.

To date, determinations of the fair value of our common stock includes valuations prepared by an independent third-party valuation specialist using methodologies, approaches and assumptions consistent with the American Institute of Certified Public Accountants Accounting and Valuation Guide: *Valuation of Privately Held Company Equity Securities Issued as Compensation* (the Practice Aid).

The Practice Aid prescribes several valuation approaches for setting the value of an enterprise, such as the cost, income and market approaches, and various methodologies for allocating the value of an enterprise to its common stock. The cost approach establishes the value of an enterprise based on the cost of reproducing or replacing the property less depreciation and functional or economic obsolescence, if present. The income approach establishes the value of an enterprise based on the present value of future cash flows that are reasonably reflective of our company's future operations, discounting to the present value with an appropriate risk adjusted discount rate or capitalization rate. The market approach is based on the assumption that the value of an asset is equal to the value of a substitute asset with the same characteristics. Each valuation methodology was considered in our valuations.

We estimated the enterprise value of our business using a market approach. In accordance with the Practice Aid, we considered the various methods for allocating the enterprise value across our classes and series of capital stock to determine the fair value of our common stock at each valuation date. Based on our stage of development and other relevant factors, we concluded that the Option Pricing Method (OPM) was most appropriate for the valuation of our common stock performed by an independent third-party valuation specialist. We believed the OPM was the most appropriate given the expectation of various potential liquidity outcomes and the difficulty of selecting and supporting appropriate enterprise values given our early stage of development. Under the OPM, shares are valued by creating a series of call options with exercise prices based on the liquidation preferences and conversion terms of each equity class. The values of the preferred and common stock are inferred by analyzing these options. In February 2021, as a result of our Series A and Series A-1 convertible preferred stock financing, we updated our market approach to include the back-solve method that assigns an implied enterprise value based on the most recent round of funding or investment and allows for the incorporation of the implied future benefits and risks of the investment decision assigned by an outside investor. In consideration of a potential initial public offering (IPO), we allocated enterprise value using a hybrid method of the probability weighted expected return method (PWERM), whereby the enterprise value in the IPO scenario is allocated to each class of shares using the fully-diluted shares outstanding and whereby the enterprise value in the non-IPO scenario is allocated using an OPM to reflect the full distribution of possible non-IPO outcomes. The hybrid method is useful when certain discrete future outcomes can be predicted, but also accounts for uncertainty regarding the timing or likelihood of specific alternative exit events.

The assumptions underlying these valuations represented management's best estimates, which involved inherent uncertainties and the application of management's judgment. As a result, if we had used significantly different assumptions or estimates, the fair value of our common stock and our stock-based compensation expense could have been materially different. Following the closing of this offering, our board of directors will determine the fair value of our common stock based on its closing price as reported on the date of grant on the primary stock exchange on which our common stock is traded.

Other Company Information

Jumpstart Our Business Startups Act ("JOBS Act")

We are an emerging growth company, as defined in the JOBS Act, and we may remain an emerging growth company for up to five years following the closing of this offering. For so long as we remain an emerging growth company, we are permitted and intend to rely on certain exemptions from various public company reporting requirements, including not being required to have our internal control over financial reporting audited by our independent registered public accounting firm pursuant to Section 404(b) of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and any golden parachute payments not previously approved. In particular, in this prospectus, we have provided only two years of audited consolidated financial statements and have not included all of the executive compensation-related information that would be required if we were not an emerging growth company. Accordingly, the information contained herein may be different than the information you receive from other public companies in which you hold stock.

Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. We will remain an emerging growth company until the earlier of (i) the last day of the fiscal year (a) following the fifth anniversary of the closing of this offering, (b) in which we have total annual gross revenue of at least $1.07 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700.0 million as of the prior June 30th, and (ii) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

We are also a "smaller reporting company" because the market value of our stock held by non-affiliates plus the proposed aggregate amount of gross proceeds to us as a result of this offering is less than $700 million as of June 30, 2019 and our annual revenue was less than $100 million during the fiscal year ended December 31, 2020. We may continue to be a smaller reporting company after this offering in any given year if either (i) the market value of our stock held by non-affiliates is less than $250 million as of June 30 in the most recently completed fiscal year or (ii) our annual revenue is less than $100 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700 million as of June 30 in the most recently completed fiscal year. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited consolidated financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

Recent Accounting Pronouncements

See Note 2 to our consolidated financial statements included elsewhere in this prospectus for a description of recent accounting pronouncements applicable to our consolidated financial statements.

Quantitative and Qualitative Disclosures about Market Risk

We are exposed to market risk in the ordinary course of our business. Market risk represents the risk of loss that may impact our financial position due to adverse changes in financial market prices and rates. Our market risk exposure is primarily a result of fluctuations in interest rates. We do not hold or issue financial instruments for trading purposes.

Interest Rate Risk

Our cash and cash equivalents consist of checking, money market, and highly liquid investments that are readily convertible to cash and that have an original maturity of three months or less from date of purchase. The carrying amounts approximate fair value due to the short maturities of these instrument. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates.

Foreign Currency Risk

We have operations and hold assets in the United Kingdom and Belgium through subsidiaries as a result of an asset acquisition. The functional currency of the subsidiary is the euro and the assets and liabilities of this subsidiary are translated to U.S. dollars according to generally accepted accounting principles. Any translation impact from this subsidiary, or any other resulting gains and losses for foreign currency transactions, have to date not been significant. We do not currently engage in any hedging transactions.

Effects of Inflation

Inflation generally affects us by increasing our cost of labor and research and clinical trial costs. We do not believe that inflation has had a material effect on our results of operations during the periods presented.

Overview

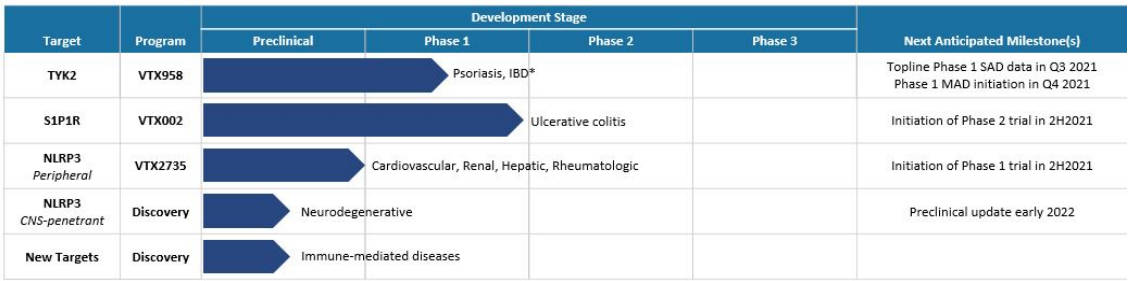
We are a clinical-stage biopharmaceutical company focused on advancing new therapies for millions of patients living with inflammatory diseases and autoimmune disorders. We believe our ability to internally discover and develop differentiated product candidates with the potential to be best-in-class and first-in-class in an efficient manner, allows us to address well-established, yet unsatisfied, multi-billion-dollar commercial markets and position us to become a leader in the immunology market.

Our lead product candidate is VTX958, a potent, oral and highly selective clinical-stage tyrosine kinase type 2 (TYK2) inhibitor, which, we believe, has best-in-class potential. Its high selectivity for TYK2 without detectable inhibition of other Janus kinase (JAK) isoforms has the potential to avoid toxicities associated with broader JAK inhibition and, thus, other JAK inhibitors. We believe VTX958 has the potential to address a broad range of immune-mediated diseases, such as psoriasis, inflammatory bowel disease (IBD), psoriatic arthritis and lupus, each of which represent multi-billion-dollar market opportunities. We plan to develop VTX958 initially for psoriasis and IBD, among other potential indications.

In addition, we are developing VTX002, a potent, oral and highly selective Phase 2-ready sphingosine 1 phosphate receptor 1 (S1P1R) modulator for ulcerative colitis (UC). S1P1R is a clinically validated target and in our Phase 1 trial VTX002 was well tolerated at all doses tested and showed a robust, dose-dependent, and steady-state reduction in absolute lymphocyte count (ALC) of up to 65%. Based on these data, we plan to initiate a Phase 2 randomized, placebo-controlled clinical trial in the second half of 2021 to pursue the commercial opportunity in UC, which represented approximately $7 billion in worldwide sales in 2020.

We also are developing a comprehensive portfolio of differentiated NOD-like receptor protein 3 (NLRP3) inhibitors to address multiple indications driven by NLRP3 inflammasome activation. Our potent, oral, highly selective and peripherally restricted (does not cross the blood-brain barrier) NLRP3 inhibitor, VTX2735, has been designed to treat systemic inflammatory diseases, such as cardiovascular, hepatic, renal and rheumatologic diseases. In addition to VTX2735, our preclinical NLRP3 inhibitor programs include central nervous system (CNS)-penetrant compounds. Any one of these inflammatory diseases represents a multi-billion-dollar commercial opportunity. VTX2735, our lead NLRP3 candidate, is expected to enter the clinic in the second half of 2021 (Figure 1).

Figure 1: Pipeline of current preclinical and clinical programs



*Following the completion of our MAD Phase 1 trial, we intend to initiate Phase 2 trials in psoriasis, IBD and potentially other indications.

VTX958 (TYK2 Inhibitor)

VTX958 is a potent, oral and highly selective inhibitor of TYK2, an intracellular signaling kinase in the JAK family. The JAK signal transduction and activator of transcription (STAT) signaling pathway is implicated in the pathogenesis of numerous inflammatory and autoimmune diseases. By inhibiting TYK2-mediated signal transduction, VTX958 has the potential to suppress chronic inflammation while avoiding inhibition of other related members of the JAK family, such as JAK1, JAK2 and JAK3, thereby reducing the associated risk of infections and other side effects. This high level of selectivity, which is based on results observed in preclinical studies, underpins a safety profile observed in preclinical studies that is differentiated from first-generation JAK inhibitors. In preclinical safety assessments in multiple species, VTX958 has demonstrated a wide safety margin, offering the possibility of exploring higher doses in human proof-of-concept (POC) studies. We believe that this could extend the clinical viability of VTX958 beyond psoriasis to IBD, lupus and other potential

indications in which higher doses may be required to achieve efficacy. We commenced a Phase 1 single-ascending dose (SAD) trial of VTX958 in healthy volunteers in March 2021. Following its completion, we plan to initiate the multiple-ascending dose (MAD) part of this trial.

VTX002 (S1P1R Modulator)

VTX002 is a potent, oral and highly selective peripherally restricted S1P1R modulator with high selectivity for the S1P1 receptor that is ready to enter Phase 2 development. In a Phase 1 trial in healthy volunteers, VTX002 was well tolerated at all doses tested with no serious adverse events. In addition, VTX002 showed a robust, dose-dependent, steady-state reduction in ALC of up to 65%. Reduction in circulating ALCs is recognized as a validated biomarker for efficacy in S1P1-mediated diseases, and S1P1 signaling has been identified as a key regulator of lymphocyte migration from lymph nodes into circulation. The blockade of this axis is emerging as a validated therapeutic approach in controlling aberrant leukocyte migration into the mucosa in IBD, suggesting clinical potential in UC patients.

Based on these Phase 1 healthy volunteer data, we plan to initiate a Phase 2 randomized, placebo-controlled clinical trial in the second half of 2021 and believe that the trial may serve as the first of two pivotal trials required for registration along with an additional Phase 3 trial. In addition, we may conduct additional clinical trials for VTX002 in other relevant immunology indications.

VTX2735 and Preclinical NLRP3 Inhibitor Portfolio

Inflammasomes are multi-protein complexes that sense molecular hallmarks of infection or cellular injury and initiate an appropriate immune response. We plan to harness the therapeutic potential of innate immune modulation with an initial focus on the NLRP3 inflammasome, one of the most widely studied members of the inflammasome family.

NLRP3 releases interleukin (IL)-1β when activated. Aberrant NLRP3 activation is involved in a range of both acute and chronic inflammatory conditions. Although several biologics targeting the downstream cytokine IL-1β have been approved for treatment of autoimmune diseases (such as Cryopyrin-Associated Periodic Syndromes (CAPS), Familial Mediterranean Fever, Still's disease, and juvenile idiopathic arthritis), we believe direct targeting of NLRP3 with an oral agent may have efficacy and safety advantages over these currently approved biologics.

VTX2735 has demonstrated potent NLRP3 inhibition in cellular assays, potent *in vivo* pharmacodynamic activity in an animal model, and high oral bioavailability in multiple non-clinical species. Preclinical safety and toxicology studies suggest that VTX2735 has a broad therapeutic window, which may allow attaining maximal target engagement in future human trials. We expect to submit an IND application for VTX2735 in the second half of 2021 and, if accepted, we intend to initiate a Phase 1 clinical trial in healthy volunteers.

Our Competitive Strengths

We believe our deep internal drug discovery and development expertise has enabled us to identify and advance multiple small molecule product candidates from preclinical studies into clinical trials in a rapid and efficient manner. Our extensive knowledge of the pathophysiology and biology of immunologic conditions informs our decision-making to advance the best scientific and clinical path to demonstrate pharmacological activity and proof-of-concept within an efficient timeframe and cost-effective budget. The infrastructure within our discovery and development capabilities includes all aspects of the drug discovery process, such as medicinal and process chemistry, computational chemistry, structural biology, and *in vitro* and *in vivo* pharmacology. Our approach to drug discovery and development allows us to work in a seamless and simultaneous manner, rather than in sequential fashion. In our TYK2 inhibitor program, for example, we initiated our Phase 1 trial in March 2021, representing a 25-month timeframe from lead identification to a first-in-human trial. We believe that our expertise will allow us to achieve similar development timelines and milestones with our earlier stage preclinical programs while mitigating some of the risks usually associated with new product development.

The key elements of our approach to discovery and development include:

- An iterative lead optimization approach that utilizes rational and empirical drug design, allowing for rapid advancement of our lead compounds and delivering drug candidates with high non-clinical potency and selectivity for our immunology targets; and
- Relevant screening methods that utilize human cellular assays and human whole blood for our lead optimization assays, including a biomarker-driven approach. We believe that this approach offers the

best and most relevant predictor of potency, efficacy and therapeutic window for our compounds in human clinical trials.

We have a diversified pipeline of promising product candidates, all of which target multi-billion-dollar commercial markets, which we believe, to date, are unsatisfied. We intend to leverage our drug discovery and development approach and expertise to advance this pipeline, and to apply our knowledge of the immunology market to augment and/or accelerate our pipeline through strategic partnerships.

Our Management Team, Executive Chair, Advisors and Investors

Our scientific and management team has decades of distinguished experience in the discovery and development of small molecule drugs, including within the immunology space, and a proven track record of advancing high-quality compounds into the clinic, some of which are successful commercial products.

Our founder and Chief Executive Officer, Raju Mohan, PhD, has over 30 years of experience in drug discovery and development, during which time he advanced 10 product candidates into the clinic for a broad range of disease indications. Dr. Mohan is an inventor of esaxerenone, which is approved and marketed as Minnebro. He started his career at Schering AG/Berlex Biosciences, Inc., followed by X-Ceptor Therapeutics, Inc., which was acquired by Exelixis, Inc. in 2004. In addition to Ventyx, he is the founder of multiple start-up biopharmaceutical companies, including Ralexar Biosciences, Inc., Akarna Therapeutics Ltd. (acquired by Allergan plc in 2016), Escalier Biosciences BV, Oppilan Pharma Ltd., Zomagen Biosciences Ltd. and Vimalan Biosciences, Inc. Our Chief Scientific Officer, John Nuss, PhD, has over 25 years of experience in drug discovery and development having advanced over 25 compounds into development, including three approved drugs: Cometriq (cabozantinib), Cotellic (cobimetinib), and Minnebro. He served in senior positions at Ferring Research Institute and Exelixis, Inc. Our Chief Financial Officer, Martin Auster, MD, most recently served as Managing Director, Biotechnology Analyst at Credit Suisse AG. Prior to Credit Suisse, he was a senior biotechnology analyst at UBS Securities LLC. Earlier, he served in senior executive positions at Ascendis Pharma A/S and United Therapeutics Corporation, and as a senior biotechnology analyst at Wachovia Securities and GLG Partners. Our Chief Business Officer, Christopher Krueger, JD, MBA, has over 20 years of operational experience in public and private biopharmaceutical companies. He most recently served as Chief Executive Officer of Oppilan Pharma Ltd. and Chief Business Officer at Zomagen Biosciences Ltd. until their acquisitions by Ventyx Biosciences, Inc. in 2021. He previously served as the Chief Business Officer of Akarna Therapeutics Ltd. until its acquisition by Allergan plc in 2016 and the Chief Business Officer of Ardea Biosciences, Inc. prior to its acquisition by AstraZeneca plc.

Our board of directors is led by Executive Chair, Sheila Gujrathi, MD, a seasoned pharmaceutical executive who has successfully built and financed biotech companies, managed complex clinical and research stage pipelines, and led the advancement and approval of multiple novel small molecule and biologic therapeutics in immunology, inflammation and oncology therapeutic areas. Dr. Gujrathi is the co-founder and former Chief Executive Officer of Gossamer Bio, Inc. Prior to Gossamer, Dr. Gujrathi served as Chief Medical Officer of Receptos, Inc. (acquired by Celgene Corporation) and was responsible for the clinical development of Zeposia (ozanimod), which is approved for multiple sclerosis and UC. Prior to Receptos, Dr. Gujrathi served as Vice President of the Global Clinical Development Group in Immunology at Bristol-Myers Squibb Company (BMS), where she led late-stage clinical development and supported numerous global regulatory filings and approvals for Orencia® and Nulojix®. Prior to BMS, Dr. Gujrathi held roles in immunology, tissue growth and repair in the clinical development groups at Genentech, Inc., where she worked on Ocrevus®, Rituxan®, Xolair®, and a number of other programs across all stages of development and served as the Avastin® franchise team leader.

Our clinical and scientific advisors are world-renowned experts in scientific and clinical development aspects of our specific immunology targets and within the inflammatory and autoimmune diseases generally, and have translational experience with human biomarkers of disease. Our Clinical and Scientific Advisory Board includes: William J. Sandborn, MD, Chief Medical Officer at Shoreline Biosciences, Inc.; James G. Krueger, MD, PhD, Director of the Milstein Medical Research Program and D. Martin Carter Professor in Clinical Investigation at The Rockefeller University; Alexa Kimball, MD, Chief Executive Officer and President of Harvard Medical Faculty Physicians at Beth Israel Deaconess Medical Center; Bruce Sands, MD, MS, the Dr. Burrill B. Crohn Professor of Medicine at the Icahn School of Medicine at Mount Sinai; Emma Guttman-Yassky, MD, PhD, System Chair of the Department of Dermatology and the Waldman Professor of Dermatology and Immunology at the Icahn School of Medicine at Mount Sinai; and, Luisa Salter-Cid, PhD, Chief Scientific Officer of Pioneering Medicines (a division of Flagship Pioneering) and former Chief Scientific Officer of Gossamer Bio, Inc. and Vice President and Head of Immunology, Small Molecule Immuno-Oncology, at BMS).

To date, we have raised over $114 million from leading life sciences investors, including venBio Partners, Third Point, RTW Investments, LP, Janus Henderson Investors, Wellington Management Company LLP, OrbiMed Advisors LLC, Surveyor Capital (a Citadel company), Farallon Capital Management, LLC, Vivo Capital, Logos Capital, Qiming Venture Partners USA, Cormorant Asset Management LLC, and New Science Ventures LLC.

Our Strategy

Our goal is to become a leader in developing differentiated, best-in-class and first-in-class product candidates in a rapid and efficient manner for the immunology market and, ultimately, to address well-established, yet unsatisfied, multi-billion-dollar commercial markets.

The three key elements to achieve this strategy include:

Focusing on the identification and development of differentiated product candidates against high-value, validated immunology targets that address efficacy and safety limitations of currently approved drugs and those in development. Specifically, we will:

- **Maximize the value of VTX958, our highly selective TYK2 inhibitor, by developing it across multiple inflammatory and autoimmune indications**. Our oral TYK2 inhibitor, VTX958, is differentiated by its high selectivity for TYK2 without detectable inhibition of other JAK isoforms, potentially allowing VTX958 to avoid toxicities associated with these targets. We believe VTX958 has the potential to address a broad range of immune diseases, including psoriasis, IBD, psoriatic arthritis and lupus, each of which represents a multi-billion-dollar market. We anticipate topline data from our Phase 1 SAD trial in the second half of 2021 and plan to advance VTX958 in a Phase 2, randomized, placebo-controlled clinical trial in psoriasis, an approximately $20 billion global market in 2020, as our lead indication.
- **Rapidly advance VTX002, our selective S1P1R modulator through clinical development in UC**. VTX002 is a potent, oral and highly selective peripherally restricted S1P1R modulator with high selectivity for S1P1R. We plan to initiate a Phase 2, randomized, placebo-controlled clinical trial in UC in the second half of 2021. We believe that the trial may serve as the first pivotal trial required for registration. We are also evaluating the potential for VTX002 in other immune-mediated diseases and disorders with pathophysiology that we believe may be addressed by S1P1R modulation.
- **Advance our portfolio of NLRP3 inhibitors, starting with VTX2735, into clinical development.** Our lead NLRP3 inhibitor, VTX2735, is a potent, oral, and highly selective small molecule inhibitor of NLRP3 that is peripherally restricted and designed for the treatment of systemic inflammatory diseases. We expect to submit an IND application for VTX2735 in the second half of 2021 and, if accepted, initiate a Phase 1 clinical trial in healthy volunteers. In addition to VTX2735, we plan to develop our portfolio of CNS-penetrant compounds and tissue-specific inhibitors, which we believe have potential therapeutic utility for the treatment of neurodegenerative diseases, such as Alzheimer's disease, and NLRP3-dependent diseases in the skin, GI tract or lung, respectively.

Pursuing efficient and informed development of product candidates by fully leveraging the capabilities of our internal small molecule discovery engine and development infrastructure.

All of our pipeline candidates have been internally discovered and developed because of the combination of our fully integrated drug discovery platform and deep experience by the management and scientific team. Our goal is to continue to leverage this infrastructure and expertise as we identify new, validated, and high-priority inflammatory and immune disease candidates to continue building our pipeline portfolio and advancing new candidates through preclinical and into clinical development. We believe we can harness our expertise to achieve efficient development timelines and milestones with our earlier-stage preclinical programs while mitigating some of the risks usually associated with new product development.

Entering into strategic partnerships that may expand and/or accelerate our programs to maximize worldwide commercial potential of our product candidates.

We have internally discovered and developed all of our pipeline product candidates. As a result, we currently hold worldwide rights to each product candidate. We may opportunistically evaluate and enter into strategic partnerships around certain product candidates, targets, geographies, or disease areas to expand the potential of our product candidates around the world.

Our Product Candidates

VTX958 (Tyrosine Kinase Type 2 (TYK2) Inhibitor)

Summary Overview of VTX958

VTX958 is a potent, oral and highly selective clinical-stage inhibitor of TYK2, an intracellular signaling kinase in the JAK family that regulates chronic inflammation in immune-mediated diseases. In preclinical studies to date, VTX958 inhibited only TYK2 and avoided inhibition of other related members of the JAK family (JAK1, JAK2 and JAK3). The inhibition of JAK1, JAK2 and JAK3 are associated with heightened risk of infections and other side effects.

We believe VTX958's leading selectivity profile and broad therapeutic window positions it as a potential best-in-class therapeutic for multiple autoimmune diseases with large commercial markets and high unmet medical need, such as psoriasis, IBD, psoriatic arthritis and lupus.

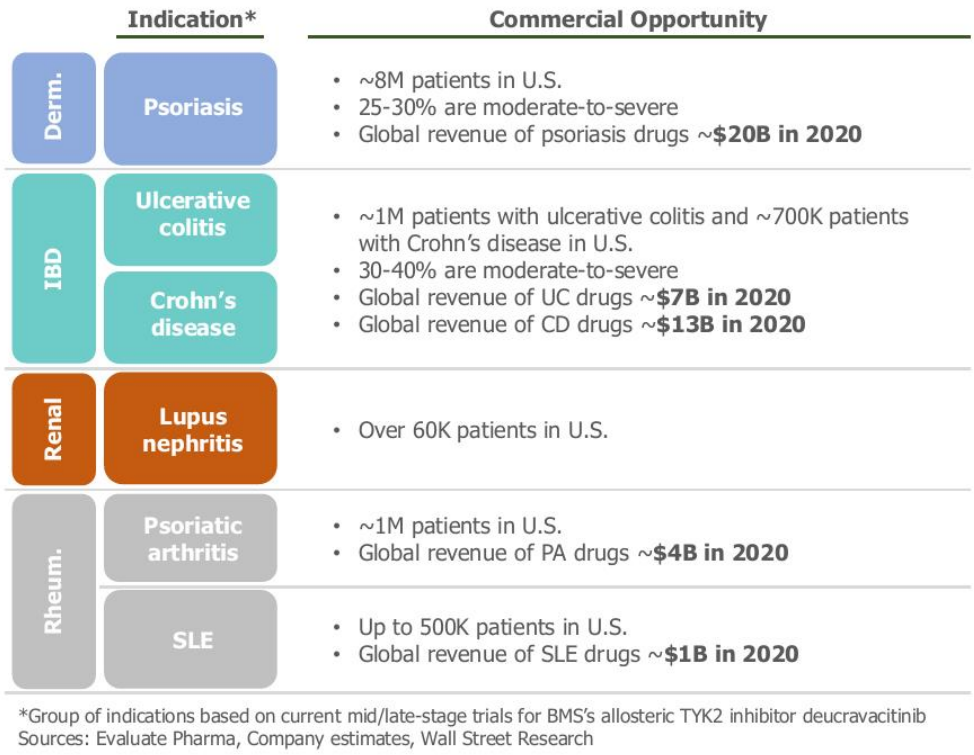
Proof-of-concept for the TYK2 inhibitor mechanism was established by BMS's TYK2 inhibitor, deucravacitinib. In two Phase 3 trials in psoriasis patients, deucravacitinib demonstrated significantly greater efficacy than Amgen's Otezla (apremilast, a small molecule inhibitor of PDE4) as measured by Psoriasis Area and Severity Index (PASI)-75 scores (indicating a 75% reduction in PASI). In addition, the PASI-75 scores of deucravacitinib were in line with those demonstrated previously with currently approved biologics.

VTX958 may be able to demonstrate a more attractive clinical profile than deucravacitinib because VTX958's higher selectivity and broader therapeutic window may allow us to explore relatively higher clinical doses and exposures. We commenced a Phase 1 SAD trial of VTX958 in healthy volunteers in March 2021. Following its completion, we plan to initiate the MAD part of this trial.

Market Opportunity

TYK2-mediated therapies have the potential to address multiple diseases that each represent multi-billion-dollar markets (Figure 2). The figure below summarizes the prevalence and market potential of each of these indications in the U.S. and globally.

Figure 2: Potential indications for TYK2-targeted molecules

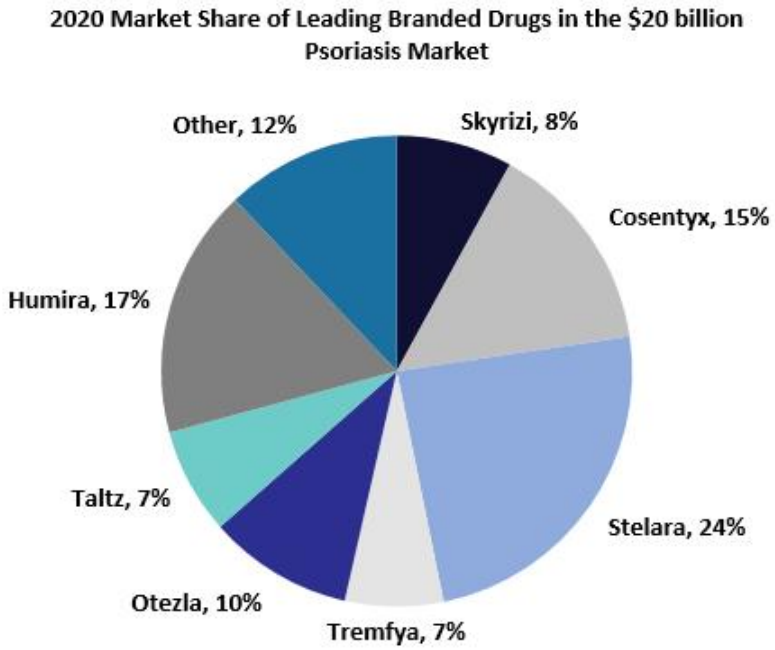


Overview of Psoriasis

Our initial indication for VTX958 is in moderate-to-severe psoriasis patients. Psoriasis is an autoimmune disease that occurs in about 2%-3% of adults in the U.S. with similar prevalence in Germany, France, Italy and Spain (EU4), and the United Kingdom. About 90% of cases are plaque psoriasis, which is characterized by "plaques", or raised, red areas of skin covered with a silver or white layer of dead skin cells referred to as "scale". Psoriatic plaques can appear on any area of the body, but most often appear on the scalp, knees, elbows, trunk and limbs, and the plaques are often itchy and sometimes painful.

Psoriasis patients are generally characterized as mild, moderate or severe, depending on the extent of involvement based on body surface area (BSA). Moderate-to-severe psoriasis is typically defined as involvement of more than 5% of the BSA and accounts for approximately 25% to 30% of the psoriasis patient population. We believe there are approximately 1.2 million moderate-to-severe psoriasis patients being treated in the U.S. and a similar population in the EU4 and the United Kingdom. Global revenues for approved products treating moderate-to-severe psoriasis totaled approximately $20 billion in 2020, including: $4.8 billion for Stelara (ustekinumab, an anti-interleukin (IL)-12/23 antibody); $3.4 billion for Humira (adalimumab, an anti-tumor necrosis factor (TNF) antibody), and: $2.9 billion for Cosentyx (secukinumab, an anti-IL-17 antibody).

Figure 3: Worldwide branded psoriasis drug sales in 2020



Treatment Paradigm in Psoriasis

Numerous topical and systemic therapies are available for the treatment of psoriasis. Treatment modalities are chosen on the basis of disease severity, relevant comorbidities, cost and convenience, efficacy and evaluation of individual patient response. Moderate-to-severe psoriasis requires phototherapy or systemic therapies, such as retinoids, methotrexate, cyclosporine, apremilast or biologic immune modifying agents. However, current treatments for moderate-to-severe psoriasis are often associated with toxicity and/or limited efficacy or loss of efficacy over time, and patients remain undertreated, representing a high unmet medical need.

Phototherapy acts through multiple mechanisms, including apoptosis of inflammatory cells and increasing production of anti-inflammatory cytokines. However, patients might be reluctant to use phototherapy due to significant insurance and co-pay costs and photosensitivity.

Treatment with non-biologic systemic therapy, such as methotrexate or apremilast, is also limited. According to Decision Resources Group, non-biologic systemic therapy represents approximately 8% of patients worldwide and 11% of patients in the U.S. The use of methotrexate has declined due to concerns about side effects and mandatory routine monitoring. Otezla's reported 2020 annual sales totaled $2.2 billion despite limitations on its use in moderate-to-severe patients, modest symptomatic improvement and frequent adverse events.

Biologic agents used in the treatment of psoriasis include the anti-TNF agents adalimumab, etanercept, infliximab and certolizumab pegol; the anti-IL-12/IL-23 antibody ustekinumab; the anti-IL-17 antibodies secukinumab and ixekizumab; the anti-IL-17 receptor antibody brodalumab; and the anti-IL-23 antibodies guselkumab, tildrakizumab and risankizumab. Treatment with biologics remains highly restricted. In the U.S., less than 20% of moderate-to-severe psoriasis patients, equivalent to approximately 6% of all psoriasis patients, are on biologic therapy. While efficacy of injectable biologics can be quite robust, with PASI-75 scores of recent approved biologics ranging as high as 61%-91%, the uptake of biologics has remained limited due to multiple factors, including the fact that they are indicated only for use in moderate-to-severe patients, their significant cost and high patient co-pays, reimbursement and access restrictions, perceived risk of side effects, and patient reluctance and fear of injections. Moreover, there are safety concerns, which limit the adoption and utility of these biologic therapies. For example, there is a concern that all TNF-alpha inhibitors have the potential to activate latent infections, such as tuberculosis, and increased rates of infection have been seen in patients with rheumatoid arthritis treated with etanercept, infliximab and adalimumab.

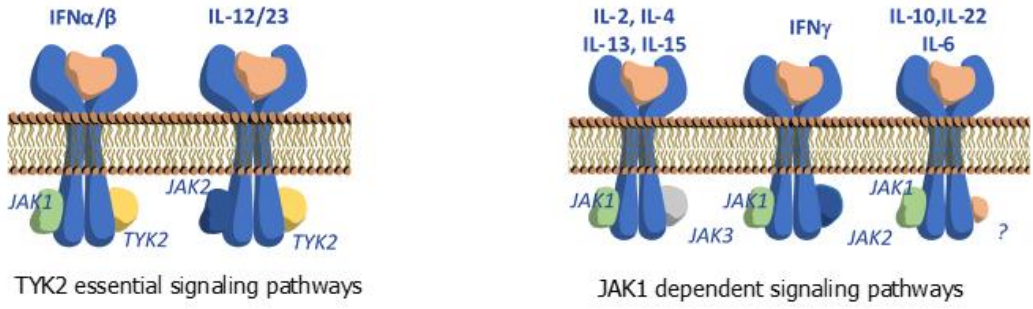
Oral TYK2 inhibitors, such as VTX958, inhibit the IL-12, IL-23 and Type I interferon pathways, which are modulated by biologic agents, such as ustekinumab, guselkumab, tildrakizumab and risankizumab. Thus far, these biologic agents are among the most effective in the treatment of moderate-to-severe psoriasis with PASI-75 scores at the upper end of reported data and PASI-90 scores approaching or exceeding 80% after 48-weeks or more of treatment. While newer biologics are typically regarded as safer than earlier-generation therapies, limitations include the need for injections, high cost of therapy, hypersensitivity reactions and long half-life in the case of an infection, providing an opportunity for safe and effective oral agents that target the same pathways.

Rationale for Targeting TYK2

Psoriasis pathogenesis is characterized by keratinocyte hyperplasia due to immunologic dysregulation predominant in T helper type 1 (Th1) and T helper type 17 (Th17) immune response signaling, which is driven by IL-12 and IL-23, respectively. Antibodies targeting IL-12 and IL-23 have been approved for the treatment of psoriasis, validating the therapeutic strategy of Th1/Th17 inhibition.

The JAK-STAT (signal transducer and activator of transcription) DNA-binding pathways are required for molecular signaling of many cytokines that are important for the differentiation and effector functions of T helper cells, including, but not limited to, IL-12 and IL-23. There are four members of the JAK family — JAK1, JAK2, JAK3 and TYK2 — all of which partner in cytokine receptor signaling (Figure 4).

Figure 4: Role of JAK family protein in cytokine receptor signaling pathways.



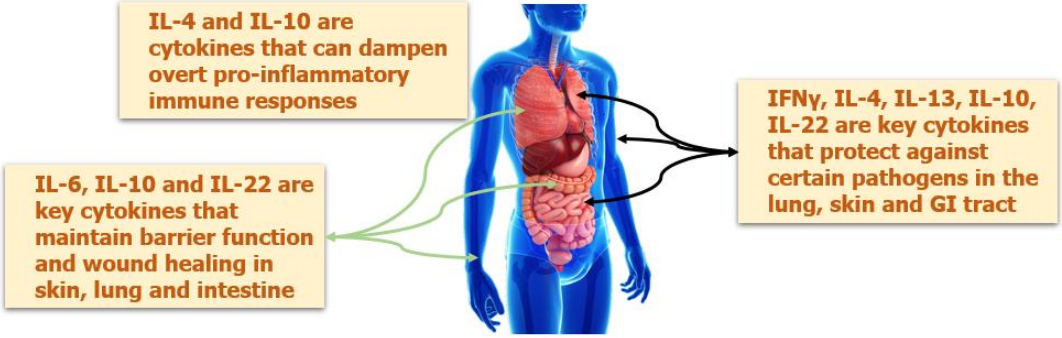
As shown in Figure 4, JAK kinases are associated with the intracellular domains of cytokine receptors and transduce receptor-mediated signals via JAK-STAT pathways. JAK1 has the broadest receptor specificity, with the ability to pair with all three other JAK family members for signal transduction. JAK2 homodimers play an essential role in cytokines essential for hematopoietic homeostasis, such as GM-CSF and EPO signaling. JAK3 mainly pairs with JAK1 for signal transduction, while TYK2 pairs with either JAK1 for IFNα/β signaling or with JAK2 for IL-12/23 signaling.

Non-specific JAK inhibitors cause undesirable side effects due to the pleotropic function of the cytokines they regulate. For example, Pfizer's pan-JAK inhibitor Xeljanz (tofacitinib) has been shown to be effective in the treatment of various psoriatic diseases. However, due to its safely profile, it has been approved only for use in psoriatic arthritis, not psoriasis.

Inhibition of JAK1 affects a broad spectrum of immune functions, including: (1) the anti-inflammatory cytokines IL-4 and IL-10; (2) the IFNγ pathway, which is important in pathogen defense; and (3) the cytokines IL-6, IL-10, and IL-22, which have important roles in maintaining mucosal barrier function. The most common serious treatment-related adverse event associated with JAK1 inhibitors is infection.

Inhibition of JAK2, which disrupts thrombopoiesis and hemopoiesis, is a major safety concern for first-generation JAK inhibitors. Second-generation JAK inhibitors that do not target JAK2, such as AbbVie's Rinvoq (upadacitinib) and Eli Lilly's Olumiant (baracitinib), have improved safety profiles, but safety concerns related to potential for toxicity related to JAK1 inhibition from regulatory agencies have contributed to black box warnings for these therapies.

Figure 5: Protective functions of cytokine pathways mediated by JAK1 that are spared by TYK2 inhibition



As shown in Figure 5, JAK1 regulates signaling downstream of many cytokines, including IFNγ, IL-4, IL-6, IL-10, IL-13 and IL-22, which have protective functions.

We believe a highly selective TYK2 inhibitor with a broad therapeutic window may be a powerful means by which to specifically address IFNα, IL-12 and IL-23-driven disease. Even though TYK2 is activated upon IL-6, IL-10 and IL-22 stimulation, it is essential only for IFNα/β, IL-12 and IL-23 signaling. We believe that a selective TYK2 inhibitor will affect only IFNα, IL-12 and IL-23 stimulated pathways, minimizing the safety concerns that likely arise from inhibition of other JAK kinases.

This hypothesis is supported by multiple genome-wide association studies that have identified human loss-of-function mutations in the TYK2 gene to be a protective factor in a variety of autoimmune diseases, including psoriasis. Immune cells with these mutations are non-responsive to IFNα/β, IL-12 and IL-23 stimulation, but maintain normal responses to IL-10 and IL-6 stimulation. Importantly, individuals with loss-of-function mutations in the TYK2 gene are healthy, without increased risk of infection, indicating selective inhibition of TYK2 may present an optimal balance between reduction of autoimmunity and preservation of anti-pathogen immune function.

All JAK kinases contain a catalytic kinase domain (JH1), where critical phosphoryl transfer reactions responsible for STAT activation occur. All JAK kinases have a second, regulatory pseudokinase domain (JH2), which is autoinhibitory and functions to maintain the kinase domain in an inactive stand-by mode until an appropriate activation signal is received. The kinase domains of JAK family members are highly conserved, making the design of selective inhibitors targeting the established kinase function challenging. The regulatory JH2 domains of the JAK kinases, however, are much less conserved and have structurally distinct binding pockets, making them attractive targets for inhibitor design.

Therefore, we have chosen to exploit these structural differences to design selective allosteric TYK2 inhibitors, typified by VTX958, which bind with high specificity to the JH2 domain of TYK2 and inhibit the kinase *via* disruption of its essential regulatory role in the signal transduction of TYK2.

We believe TYK2 is validated as a clinical target based on Phase 3 data from two trials of BMS' TYK2 inhibitor, deucravacitinib, in psoriasis, which demonstrated superior efficacy on primary endpoints compared to a leading oral agent for the treatment of psoriasis. In the two Phase 3 trials, at the primary endpoint assessed following 16 weeks of treatment, deucravacitinib patients dosed at 6 mg QD achieved PASI-75 scores of 58.7% and 53.6%, respectively, which represented a statistically significant improvement compared to apremilast's PASI-75 of 35.1% and 40.2%, respectively, and placebo PASI-75 of 12.7% and 9.4% (Table 1).

Table 1: Reported Phase 3 clinical data in psoriasis for apremilast, risankizumab and deucravacitinib

COMPOUND	TRIAL	DOSE	PASI-75*		PASI-90*		PASI-100*	
			Tx	PBO	Tx	PBO	Tx	PBO
Apremilast (PDE4 inhibitor)	ESTEEM-1[1]	30mg (BIDa Oral)	33.1	5.3	9.8	0.4	—	—
	ESTEEM-2[2]		28.8	5.8	8.8	1.5	—	—
	POETYK PSO-1[5]		35.1	12.7	—	—	—	—
	POETYK PSO-2[5]		40.2	9.4	—	—	—	—
Risankizumab (Anti-IL23A Antibody)	UltIMMa-1[3]	150 mg (SCb)	—	—	75.3	4.9	35.9	0
	UltIMMa-2[3]		—	—	74.8	2	50.7	2
	SustaIMM4	150 mg (SCb)	94.5	8.6	74.5	1.7	32.7	0
		75 mg (SCb)	89.7	8.6	75.9	1.7	22.4	0
Deucravacitinib (TYK2 inhibitor)	POETYK PSO-1[5]	6mg (QD Oral)	58.7	12.7	—	—	—	—
	POETYK PSO-2[5]		53.6	9.4	—	—	—	—

* 16 weeks treatment; BID: twice daily, QD: once daily, SC: subcutaneous injection

1 Papp et al., 2015 JAAD; [2]Paul et al., 2015 British J. Dermatology; [3]Gorden et al., 2018 The Lancet; [4]Ohtsuki et al., 2019 J. Dermatology; [5]BMS investor presentation April 23, 2021

a: titrated from 10 mg QD to 30 mg BID over the first week of dosing; b: injection on week-0, 4 and Q3W thereafter

Competition and Limitations of Current TYK2 Inhibitors

There are a number of TYK2 inhibitors with different selectivity profiles currently being investigated in clinical trials for multiple autoimmune indications. These inhibitors can be divided roughly into two groups: (1) active kinase domain inhibitors, including clinical-stage compounds, such as Pfizer's PF-06826647and Galapagos' GLPG3667, and (2) allosteric inhibitors, including deucravacitinib from BMS, an undisclosed lead compound from Nimbus Therapeutics, Inc. and ESK-001 from Esker Therapeutics, Inc. (Table 2).

Table 2: Publicly disclosed TYK2 inhibitor programs

	COMPANY	COMPOUND	STAGE	NOTE:
Active Domain	Pfizer	PF-06826647	Phase 2	Non-specific for TYK2
	Galapagos	GLPG3667	Phase 2	Non-specific for TYK2
Allosteric	BMS	Deucravacitinib	Phase 3	
	Nimbus	Undisclosed	Phase 1	
	Esker	ESK-001	Phase 1	

Designing selective JAK inhibitors that directly and specifically inhibit the intended kinase function is challenging due to the structural similarity between kinase domain (JH1) ATP binding pockets of JAK family members. For example, based on published data, PF-06826647, an active domain inhibitor, has less than six- fold selectivity between JAK2 and TYK2 in kinase assays. In a Phase 1b clinical trial of PF-06826647, a dose-dependent decrease in reticulocytes was observed and was postulated by the investigators to be due to inhibition of EPO-JAK2 signaling at higher doses.

Allosteric inhibitors that bind to the regulatory pseudokinase JH2 domain have better selectivity for TYK2, but high homology between the JAK1 and TYK2 JH2 domains remains a challenge in designing selective agents. For example, while deucravacitinib is a potent binder to the TYK2 JH2 domain, it also shows sub-nanomolar

potency in a JAK1-JH2 binding assay. This interaction with the JAK1-JH2 pathway is reflected in downstream signaling in IL-10 and IL-6 stimulation assays.

Table 3: Published *in vitro* assay results for TYK2 inhibitors PF-06826647 and deucravacitinib

		PF-06826647[1]	DEUCRAVACITINIB[2]
Biochemical assays		IC_{50}	Kd
	TYK2 kinase	17 nM	—
	JAK2 kinase	74 nM	—
	TYK2 JH2 binding	—	0.02 nM
	JAK1 JH2 binding	—	1 nM
Cellular cytokine stimulation assays	IC50	IC_{50}	
	IL-23 PBMC	66 nM	9 nM
	IFNg PBMC	—	3 nM
	IL-12 WB	53 nM	—
	IL-12 PBMC	—	11 nM
	IL-23 WB	112 nM	—
TYK2 pathway cytokines	IL-23 PBMC		9 nM
	IL-6 PBMC	427 nM	6 nM
JAK1 pathway cytokines	IL-6 PBMC	—	100 nM

WB=whole blood; PBMC=peripheral blood mononuclear cells; [1] Gerstenberger et al., 2020 J. Med. Chem.; [2] Burke et al., 2019 Science Translational Medicine and Wrobleski et al., 2019 J. Med. Chem.

We believe that less selective TYK2 inhibitors may produce toxicity arising from off-target effects when used at higher doses. Moreover, dose constraints on less selective compounds may result in sub-optimal inhibition of key pathways (i.e., IL-12, IL-23) that are relevant to targeting autoimmune conditions, such as psoriasis and IBD, and, ultimately, yield lower efficacy, particularly in those indications in which increased efficacy may require elevated dose levels of a TYK2 inhibitor.

Our Solution: VTX958

VTX958 is a potent, oral and highly selective allosteric inhibitor of TYK2 with a highly selective profile for TYK2 over other members of the JAK family. VTX958 was designed to inhibit IL-12, IL-23 and Type 1 interferon (IFNα/β) by binding selectively to the pseudokinase JH2 regulatory domain of TYK2, without inhibiting the analogous domains of JAK1, JAK2, or JAK3.

We believe that TYK2 inhibitors represent a new class of oral drugs that target pathways only partially addressed by current IL-12/IL-23 biologic therapies. A selective allosteric TYK2 inhibitor may play a critical role in offering a well-balanced therapy that: (1) mitigates harmful immune responses in these diseases while preserving protective immunity against pathogens; (2) avoids risk of injection-related reactions, including hypersensitivity; (3) overcomes patient reluctance to injections, thus potentially minimizing discontinuation rates; and (4) may be better positioned to address the cost and access limitations frequently associated with biologic therapies.

Table 4a: Binding of VTX958 and deucravacitinib to JH2 domains (Ventyx data)

	VTX958	DEUCRAVACITINIB
TYK2-JH2 Binding Kd	0.058 nM	0.009 nM
JAK1-JH2 Binding Kd	240nM	0.43 nM
Selectivity (fold)	>4,000	48

We have internally conducted pseudokinase domain binding assays comparing VTX958 and deucravacitinib and have demonstrated that VTX958 has > 4000-fold selectivity for its binding to the TYK2 JH2 domain as compared to its binding to the JAK1 JH2 domain. Deucravacitinib, by comparison, has high affinity for both TYK2 JH2 and JAK1 JH2 domains, binding with sub-nanomolar affinity to both domains with 48-fold selectivity. Our internal studies showed that VTX958 is approximately 80-fold more selective compared to deucravacitinib

in its binding affinity for the TYK2 JH2-allosteric domain (Table 4a) and, we believe, that this selectivity is also reflected in the higher selectivity of VTX958 for TYK2 relative to deucravacitinib in cellular cytokine assays.

Table 4b: Head-to-head comparison of cellular potencies between VTX958 and deucravacitinib (Ventyx data)

PRIMARY DRIVER	CYTOKINE/CELL SYSTEM	VTX958 IC50	DEUCRAVACITINIB IC_{50}
TYK2 Pathways	IFNα PBMC	12 nM	5 nM
	IFNα WB	170 nM	32 nM
	IL-12 PBMC	21 nM	10 nM
	IL-12 WB	324 nM	78 nM
	IL-23 PBMC	5 nM	10 nM
	IL-12 + IL-18 PBMC	35 nM	8 nM
JAK1 Pathways	IL-22 PBMC	>10,000 nM	114 nM
	IL-10 PBMC	>10,000 nM	20 nM
	IFNg PBMC	>10,000 nM	114 nM
	IL-4 PBMC	>10,000 nM	249 nM
	IL-6 PBMC	>10,000 nM	516 nM

As shown in Table 4b, VTX958 shows high selectivity for TYK2-mediated cytokine pathways over JAK1-mediated pathways in multiple cellular cytokine stimulation assays conducted in both peripheral blood mononuclear cells (PBMC) and in human whole blood (WB). This selective effect on TYK2-driven pathways differentiates VTX958 from more advanced TYK2 inhibitors in clinical development. Importantly, VTX958 was shown to have no detectable effect on JAK1-driven cytokines, including IL-6 and IL-10, whereas deucravacitinib has been shown, by us and by others, to inhibit activity on these pathways from 20-500 nM.

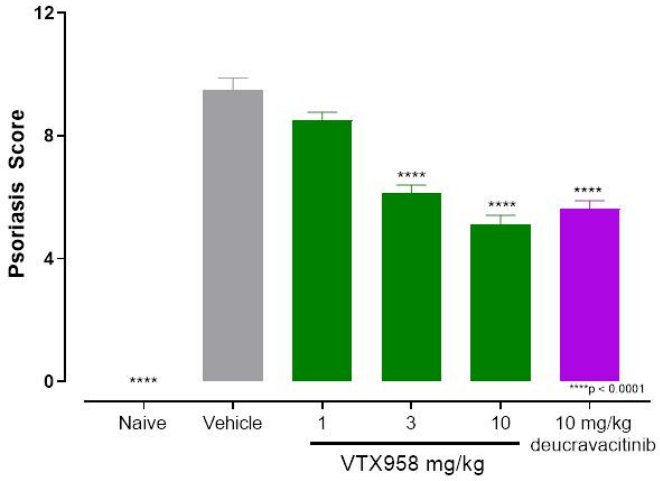
Due to its class-leading selectivity profile and broad therapeutic window, we believe VTX958 has the potential to be a best-in-class therapeutic for multiple autoimmune diseases with large commercial markets and high unmet medical need, such as psoriasis, IBD and potentially psoriatic arthritis and lupus.

Summary of VTX958 Preclinical Data

We believe VTX958 compares favorably to other allosteric TYK2 inhibitors, such as deucravacitinib, and to active kinase domain TYK2 inhibitors, such as PF-06826647, with respect to the effect on TYK2-driven cytokine signaling. Moreover, VTX958 had no detectable effect on JAK1-driven cytokines, including IL-10 and IL-6, and, therefore, has the potential to avoid effects mediated by IL-6-signaling on intestinal epithelial cells and other side effects potentially attributable to JAK1 inhibition, such as acne, infection and shingles.

As shown in Figure 6, VTX958 has demonstrated activity comparable to deucravacitinib in an imiquimod-induced psoriasis model in mouse. In this model, imiquimod cream was applied to establish psoriasis-like symptoms in all groups (except the naïve group). Animals were treated orally with either vehicle or with VTX958 at 1 mg/kg, 3 mg/kg, or 10 mg/kg dosed twice daily for five (5) days. Deucravacitinib was included at 10 mg/kg twice daily for comparison. The severity of psoriasis was monitored and graded daily using a modified PASI scoring system, which consists of visual measures for skin erythema, scaling and thickness.

Figure 6: Effects of VTX958 and deucravacitinib on psoriasis score in an imiquimod-induced mouse model



In support of our IND application, GLP-compliant toxicology studies were conducted in Sprague Dawley rats and cynomolgus monkeys to assess the potential toxicity of VTX958. We believe that the results of our preclinical safety studies suggest VTX958 can be dosed safely across the expected therapeutic range in humans.

Ongoing Phase 1 SAD Clinical Trial

We began dosing healthy volunteers in a Phase 1 SAD trial in March 2021 to evaluate the tolerability and pharmacokinetics of VTX958. In our Phase 1 SAD trial, we plan to dose up to seven dose cohorts, with Phase 1 dose levels ranging below and above the expected therapeutic range. Each cohort is expected to enroll six healthy volunteers who will receive VTX958 and two healthy volunteers who will be dosed with placebo as controls. We also are conducting a pharmacodynamic biomarker study as part of our Phase 1 trial.

Clinical Development Plan for VTX958

Upon completion of the SAD portion of our Phase 1 trial, we plan to initiate the MAD portion in . In addition to safety and exposure of VTX958 across multiple doses, we expect to explore the drug's impact on TYK2-driven biomarkers relevant to the pathology of psoriasis and other target indications in healthy volunteers. Following completion of the MAD portion of the Phase 1 trial to establish the therapeutic dose range for VTX958, we plan to initiate Phase 2 POC trials in psoriasis, IBD and potentially other relevant immune-mediated indications, which may include psoriatic arthritis and lupus.

VTX002 (Sphingosine 1 Phosphate Receptor (S1P1R) Modulator)

Summary Overview of VTX002

VTX002 is a potent, oral and highly selective peripherally restricted, S1P1R modulator with high selectivity for the S1P1 receptor, which we are developing for the treatment of IBD and other inflammatory indications. UC is our lead indication. S1P1 signaling has been identified as a key regulator of lymphocyte migration from lymph nodes into circulation. The blockade of this axis is a new therapeutic approach to control aberrant leukocyte migration into the mucosa in IBD.

In a Phase 1 trial in healthy volunteers, VTX002 demonstrated a robust, dose-dependent, steady-state reduction in absolute lymphocyte counts of up to 65%. Reduction in absolute lymphocyte counts is an established biomarker for S1P1-mediated pharmacodynamic effects that correlates with efficacy as demonstrated in multiple Phase 2 and Phase 3 trials conducted by third parties. VTX002 was well tolerated with no serious adverse events. Given these encouraging results, we plan to initiate a Phase 2 randomized, placebo-controlled, clinical trial in UC in the second half of 2021.

BMS' Zeposia (ozanimod) became the first S1P1R modulator approved for treatment of UC in May 2021. However, based on VTX002's effects on lymphocyte lowering in our Phase 1 trial, as well as its pharmacokinetic properties that allow for rapid onset of activity and rapid normalization of lymphocyte counts

upon discontinuation of therapy, may lead to an improved clinical profile relative to ozanimod. Further, based on the lack of liver function test elevations in our Phase 1 trial and our peripherally restricted drug activity, we believe VTX002 may avoid certain warnings included within the Zeposia label, including those around liver injury and macular edema screening, respectively.

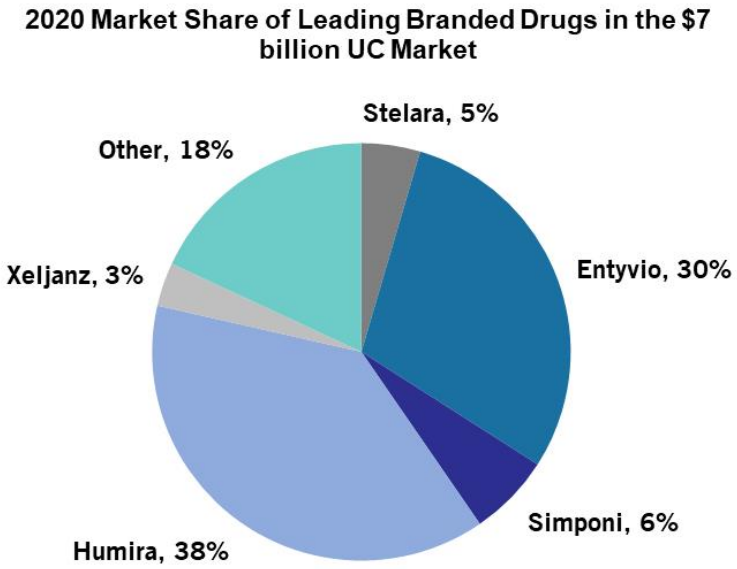
In addition to UC, we may conduct additional trials of VTX002 in other relevant inflammatory conditions that we believe may be responsive to treatment with our potent, oral and highly selective S1P1R modulator.

Overview of the IBD Market Opportunity

IBD is estimated to affect approximately 1,700,000 people in the U.S. and over 6,800,000 people globally. Incidence of IBD has been noted to be increasing in recent years, with CDC reports indicating that patients reporting as IBD sufferers has increased by up to 50% over the previous 15-20 years in the U.S. Diagnosis of IBD is split roughly between two indications: UC and Crohn's disease (CD). Approximately 30-40% of patients with each disease may be considered to have moderate-to-severe disease and represent the target population for VTX002.

In 2020, the IBD market was approximately $14 billion in the U.S. and $20 billion globally, with the UC segment representing approximately $7 billion in 2020 sales. Market research suggests the IBD commercial market has significant growth potential driven by increasing disease incidence and the emergence of novel oral therapeutics, several of which are expected to potentially seek regulatory approval over the next several years. The UC market is currently dominated by parenteral biologic agents, led by AbbVie's Humira and Takeda's Entyvio. We believe that the recent label expansion into UC for BMS' Zeposia, an S1P1R modulator, will facilitate novel oral agents to increase their share of the UC market in future years. We expect gains for oral agents to be supported by physician and patient preference for oral administration over injectable biological therapies, high demand for new therapies with improved safety profiles, and the potential for potent and well-tolerated oral agents to expand the overall treated moderate-to-severe UC population.

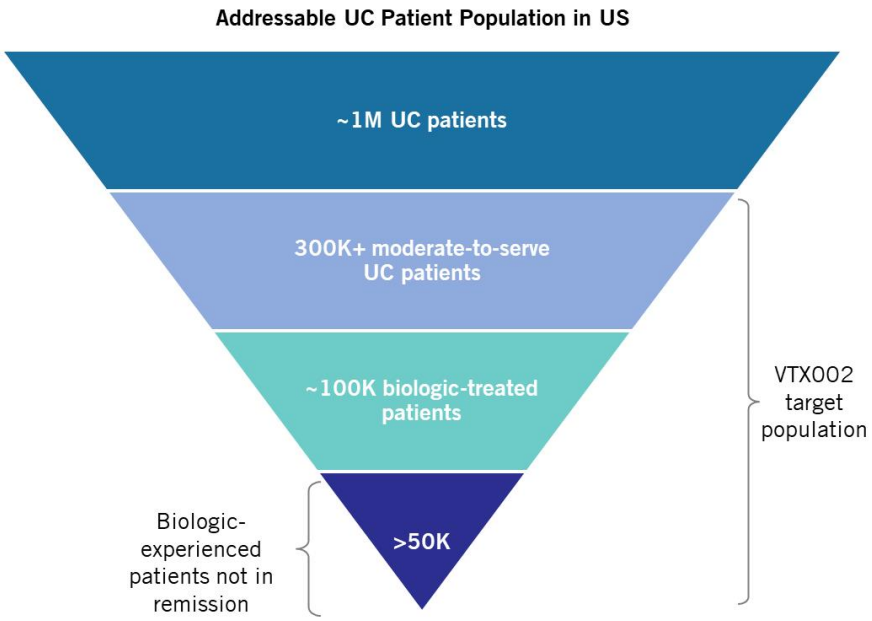
Figure 7: Worldwide branded UC drug sales in 2020



We believe that biologics have underpenetrated the UC market in the U.S. because of the aforementioned limitations associated with biologic therapy. While there are more than an estimated 300,000 moderate-to-severe UC patients in the U.S., we currently estimate only about 100,000 or more of this target patient population are on biologic treatments. We believe up to half or more of the U.S. population of UC patients treated with biologics either fail to achieve remission or lose remission over time on their current biologic

therapy, representing a segment of patients with high unmet need within the overall addressable moderate-to-severe UC market.

Figure 8: U.S. addressable UC patient population for VTX002



Overview of IBD

IBD is a complex disease with many contributing factors, including genetic, environmental and immunologic. UC and CD are the two most common forms of IBD and are characterized by dysregulation of lymphocytes contributing to inflammation. Both UC and CD are chronic, relapsing, remitting, inflammatory conditions of the GI tract that begin most commonly during adolescence and young adulthood. UC involves the innermost lining of the large intestine, and symptoms include abdominal pain and diarrhea, frequently with blood and mucus. CD can affect the entire thickness of the bowel wall and all parts of the GI tract from mouth to anus. CD symptoms include abdominal pain, diarrhea and other more systemic symptoms, such as weight loss, nutritional deficiencies and fever.

Treatment Paradigm in IBD

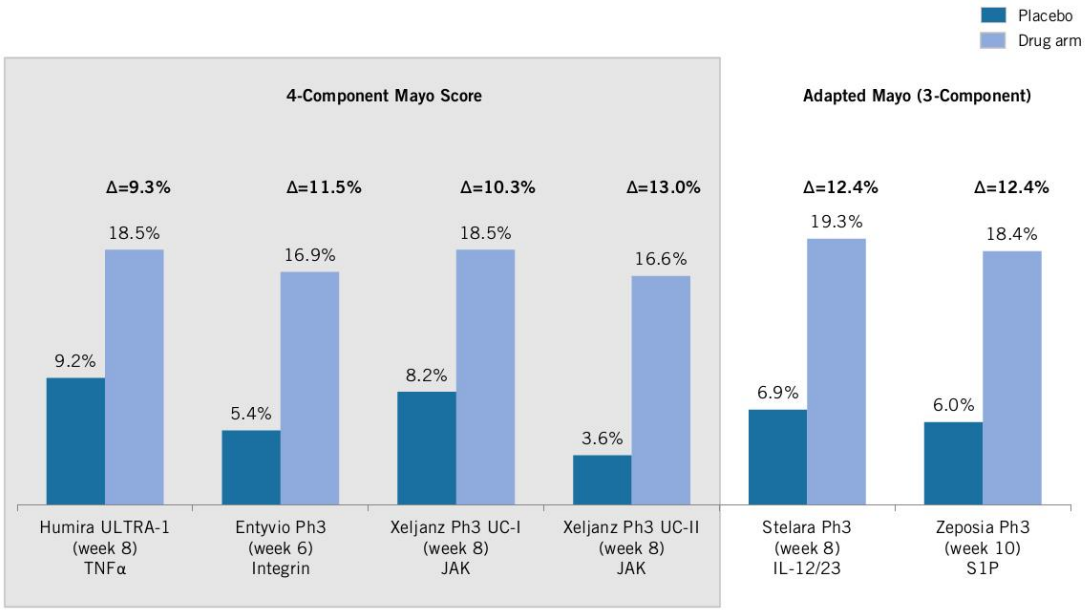
Mild-to-moderate IBD patients are commonly managed with 5-ASA (aminosalicylate) (mainly used in UC), corticosteroids or other immunosuppressive agents, including azathioprine and 6-mercaptopurine. Patients with a more serious initial disease presentation and those who have progressed or are intolerant of earlier line therapies frequently advance to biologic or novel oral medications (Figure 8). The mainstay biologics for treatment of moderate-to-severe UC and/or CD are anti-TNFα biologics (including AbbVie's Humira, Johnson & Johnson's Remicade and Simponi, and UCB Pharma's Cimzia). Recently, treatment paradigms have begun shifting as additional options and more data become available with anti-integrin therapies (particularly Takeda's Entyvio) gaining traction in UC, and anti-IL-12/IL-23 biologics (namely, Johnson & Johnson's Stelara) frequently being used in CD. BMS' Zeposia, an S1P1R modulator, was approved for treatment of moderate-to-severe UC in May 2021. Pfizer's oral JAK inhibitor, Xeljanz, was approved for treatment of UC in 2018, but commercial uptake has been limited due to its "black box" warning for risks, including serious infections, malignancy and thrombosis.

However, substantial unmet need remains as approved therapies have generally failed to demonstrate a clinical remission effect size exceeding 10-15% relative to placebo in pivotal trials. Moreover, among those patients who do respond to therapy, up to 45-50% may lose response over time, owing to development of neutralizing antibodies or other issues. Modestly stronger remission rates have been reported recently from other therapies in late-stage development, including in AbbVie's Phase 3 trials for JAK inhibitor Rinvoq (UC) and anti-IL-23 mAb Skyrizi (risankizumab-rzaa) (CD). These therapies have delivered effect sizes in the 20-

30% range, but safety issues associated with the JAK inhibitor class and the need for injections with anti-IL-23 biologics may limit market share potential.

In the UC market, there remains high unmet medical need as approved agents, including AbbVie's Humira, Takeda's Entyvio, Pfizer's Xeljanz, Janssen's Stelara and BMS' Zeposia, have achieved clinical remission rates below 20% in registration trials on either the 4-Component Mayo Score or the current standard for approval, the 3-Component Mayo Score . The treatment effect relative to placebo for approved agents has been consistently below 15% among approved UC drugs.

Figure 9: Clinical trial data for approved UC treatments



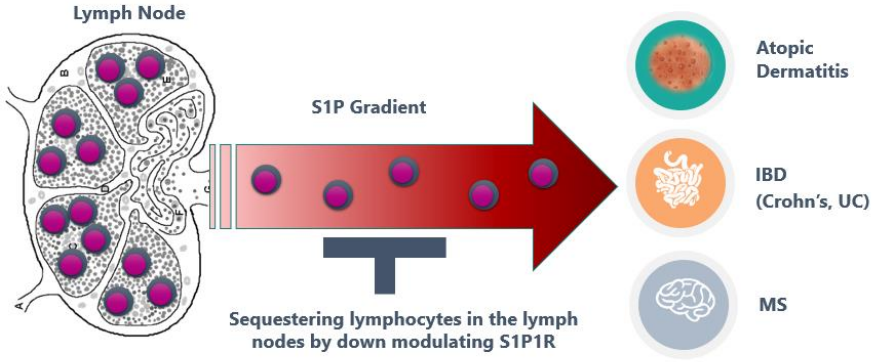
We believe there remains significant demand for well-tolerated and efficacious oral agents for the treatment of moderate-to-severe CD and UC. According to studies, nearly half of patients taking biologic therapies may be expected to experience reduced efficacy over time leading to use of higher doses at substantially higher costs and elevated rates of drug discontinuation. Many moderate-to-severe CD and UC patients refuse or are reluctant to adopt parenteral therapies, which, we believe, has contributed to a significant number of patients receiving sub-optimal care. The relapsing-remitting nature of IBD also may contribute to poor outcomes as patients may seek to discontinue therapies with undesirable or cumbersome administration during periods in which disease symptoms have abated.

Rationale for Targeting S1P1R

S1P1R is a clinically validated target, as evidenced by the approval of BMS' Zeposia (ozanimod) for UC and multiple sclerosis (MS), Novartis' marketed therapies for MS, Mayzent (siponimod) and Gilenya (fingolimod), and Johnson & Johnson's Ponvory (ponesimod).

S1P1R is a member of the sphingosine 1-phosphate receptor family of G protein coupled receptors (GPCRs). S1P1R is highly expressed on lymphocytes associated with the underlying inflammation of autoimmune diseases. S1P1R modulation causes selective and reversible retention, or sequestration, of circulating white blood cells (lymphocytes) in peripheral lymphoid tissue (such as the lymph nodes) and in the thymus. The sequestration of lymphocytes is achieved by modulating cell migration patterns (known as lymphocyte trafficking), specifically preventing self-targeting, or autoreactive, lymphocyte migration to areas of disease inflammation, which is a major contributor to autoimmune diseases, including UC (Figure 10).

Figure 10: S1P1R modulation results in sequestration of lymphocytes, ameliorating lymphocyte-driven autoimmune diseases



Summary Clinical Results of Other S1P1R Modulators in UC Trials

Based on Phase 2 data of ozanimod and etrasimod from Arena Pharmaceuticals in UC, dose-dependent reduction in peripheral lymphocyte counts has correlated generally with efficacy measures. Absolute lymphocyte reduction at efficacious dose levels were 40% for etrasimod and 49% for ozanimod.

Competition and Limitations of Current S1P1R Modulators for IBD

In May 2021, ozanimod became the first S1P1R modulator approved for the treatment of UC. In top-line results from a 645-patient, Phase 3 trial in UC, ozanimod showed moderate clinical efficacy with 18.4% of UC patients taking ozanimod achieving clinical remission compared to 6.0% of patients taking placebo. Currently, it is being studied in Phase 3 trials for the treatment of CD. Several other S1P1R modulators are in development for the treatment of UC or CD, including etrasimod, for which top-line Phase 3 data in UC are expected in the first half of 2022; CBP-307 from Connect Biopharma, currently in a Phase 2 trial for UC; and amiselimod from Bausch Health, which is expected to enter Phase 2 in 2021. These compounds previously were developed as treatments for MS and, thus, have high CNS penetration. We believe that this property may contribute to efficacy in MS, but is not desirable in IBD. The clinical safety and efficacy profile of these compounds may be limited by issues, such as hepatotoxicity; inability to dose to upper end of tolerated dose range; longer half-life in humans (for compounds with active circulating metabolites, such as ozanimod); and heart rate effects (on-target first-dose reduction in heart rate, which can be mitigated by dose titration as we demonstrated in our Phase 1 trial).

Our Solution: VTX002

VTX002 is a potent, oral and highly selective peripherally restricted S1P1R modulator designed to have high specificity for S1P1R with no detectable activity against the S1P2 and S1P3 receptors, which are associated with cardiovascular and pulmonary risks (Figure 11). VTX002 has very low CNS penetration and ocular distribution which, we believe, may reduce the risk of serious complications of S1P1R modulation in CNS, including macular edema.

Figure 11: VTX002 selectivity profile

S1P Receptor	S1P1R	S1P2R	S1P3R	S1P4R	S1P5R
EC_{50} (nM)	13	> 10,000	> 10,000	> 10,000	100

In our Phase 1 trial, VTX002 was well-tolerated with no serious adverse events or notable safety findings. In the therapeutic active dosing range tested, VTX002 showed dose-dependent steady-state reduction in absolute lymphocyte count of up to 65% which, we believe, is strongly predictive of likely clinical effect in UC and potentially other conditions. In addition, we established a dose titration schedule in the Phase 1 MAD trial to mitigate known first-dose heart rate effects associated with this class of drugs.

VTX002's wide therapeutic index allows us to explore the upper end of the dosing range, which may translate into clinical efficacy in certain indications. VTX002 has a half-life of 20 hours and no long-acting active metabolites, which enables a rapid onset of action and rapid recovery from pharmacologic activity compared to other agents, such as ozanimod.

Specifically, ozanimod's activity is achieved largely through circulating active metabolites, which can have an effective half-life of around 11 days (compared to a half-life of approximately 21 hours for ozanimod itself). This extended circulating half-life can lead to a slower time of onset of pharmacologic activity, which may result in a longer time to achieve maximal efficacy. In addition, the extended circulating half-life may introduce potential safety risk in the event of a serious infection because lymphocyte counts may take longer to rebound to normal circulating levels than with a shorter-acting agent, such as VTX002.

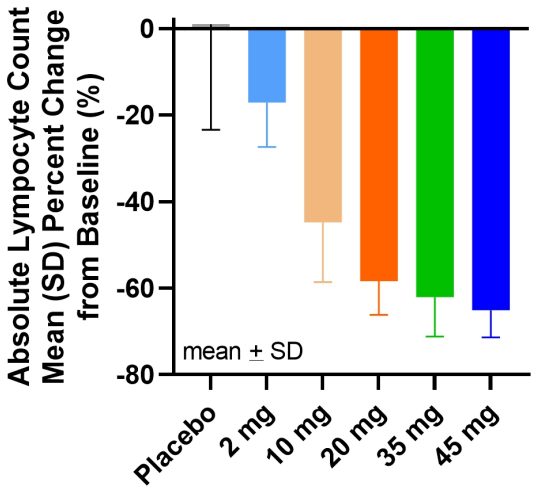
We believe VTX002 has the potential to be a best-in-class modulator of S1P1R in multiple, large autoimmune diseases. In addition to UC and MS, S1P1R modulators have previously been evaluated through Phase 2 studies in CD.

Summary of VTX002 Phase 1 Clinical Data

In the Phase 1 double-blind, placebo-controlled SAD and MAD trials in 88 healthy volunteers, once-daily dosing of VTX002 was well tolerated for up to 28 days. The trials were designed to evaluate the safety, tolerability, dose-response, pharmacokinetics and pharmacodynamics of VTX002 compared to placebo. There were no serious adverse events reported. No subjects had liver function test elevations, pulmonary function or ocular exam abnormalities, or other notable safety findings, which have been seen with other S1P1R modulators.

In the Phase 1 MAD trial, once-daily dosing of VTX002 led to a dose-dependent steady state reduction in absolute lymphocyte count of up to 65% (Figure 12). Following the last dose of VTX002 in the MAD cohorts, lymphocyte counts started to return to normal within 72 hours.

Figure 12: Placebo adjusted lymphocyte count in MAD trial of VTX002



No clinically significant first-dose reduction in heart rate was observed following treatment with VTX002 at expected therapeutic dose levels following our 7-day titration schedule.

Clinical Development Plan for VTX002

We plan to commence a Phase 2, randomized, placebo-controlled, clinical trial in approximately 180 moderate-to-severe UC patients in. The Phase 2 trial, which was designed with FDA input, is a 13-week induction study followed by a 39-week open label extension (OLE). The Phase 2 trial will provide dose/exposure/PD response data for two dose levels and supports dose selection for the Phase 3 trial. Our planned primary endpoint at Week 13 is clinical remission as defined by the 3-Component Mayo Score, which evaluates stool frequency, rectal bleeding and endoscopic results. Significant improvement on the 3-Component Mayo Score has been the primary endpoint serving as the basis for approval of recent UC therapies, including ozanimod. Other key planned secondary endpoints include endoscopic and symptomatic improvement measures. We anticipate that this trial will serve as the first pivotal study required for FDA registration.

VTX2735 and Preclinical NLRP3 Inhibitor Portfolio

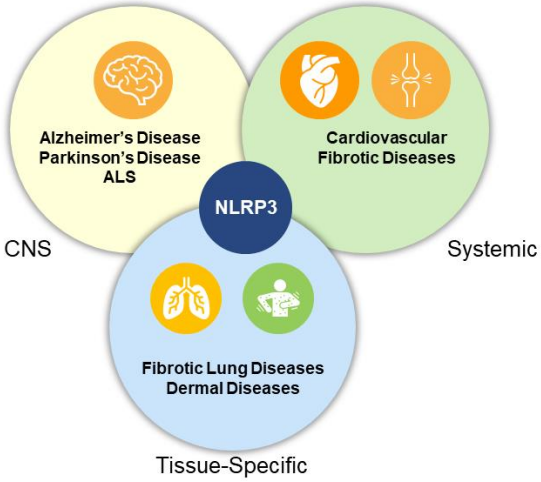
NLRP3 Inhibitor Portfolio and Peripheral NLRP3 Inhibitor VTX2735

We have several preclinical programs focused on inhibitors of inflammasomes, multi-protein complexes that sense molecular hallmarks of infection or cellular injury and initiate an appropriate immune response. Inflammasomes have been recognized for their crucial role in host defense against pathogens, but dysregulated inflammasome activation is linked to the development of autoimmune, metabolic and neurodegenerative diseases, implicating them in a broad range of inflammatory diseases. These include systemic (i.e., cardiovascular (CV) and fibrotic diseases), CNS (i.e., Alzheimer's disease, Parkinson's disease) and tissue-specific (i.e., gut, skin and lung) diseases (Figure 13).

We plan to harness the therapeutic potential of innate immune modulation, with an initial focus on the NLRP3 inflammasome. NLRP3 is the most widely studied member of the inflammasome family with the broadest role in autoimmune dysregulation and thus a high-value target for the treatment of multiple anti-inflammatory diseases.

We are developing a comprehensive portfolio of differentiated NLRP3 inhibitors to address multiple indications driven by aberrant NLRP3 activation. Our lead peripherally restricted NLRP3 inhibitor, VTX2735, is expected to enter the clinic in the second half of 2021. In addition to VTX2735, we have preclinical NLRP3 inhibitor programs directed at the CNS, as well as tissue-selective NLRP3 inhibitors for localized inflammatory diseases in the skin, GI tract or lung.

Figure 13: Potential indications for NLRP3 inflammasome inhibitors



Summary Overview of VTX2735

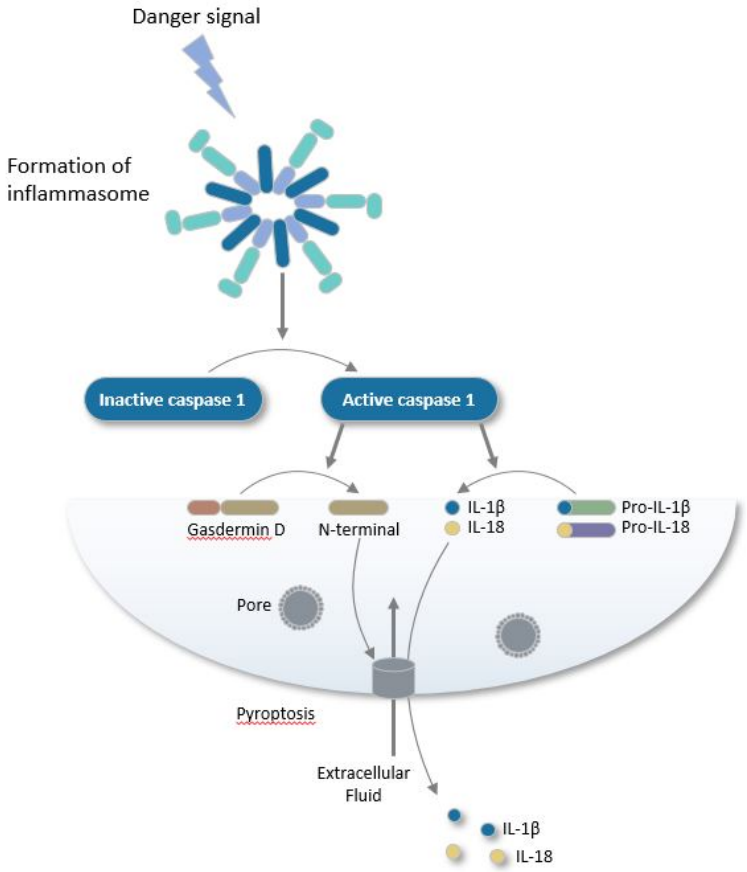
VTX2735 is a potent, oral and highly selective small molecule inhibitor of NLRP3 that is peripherally-restricted and designed for the treatment of systemic cardiovascular, hepatic, renal and rheumatologic inflammatory diseases. Aberrant NLRP3 activation results in the release of IL-1β resulting in the exacerbation of a range of both acute and chronic inflammatory conditions. Several agents targeting the downstream cytokine IL-1β have been approved for treatment of inflammatory disease, such as CAPS, Familial Mediterranean Fever, Still's disease and juvenile idiopathic arthritis. However, targeting NLRP3 directly may have efficacy and safety advantages over these approved biologics.

Preclinical safety studies suggest that VTX2735 has a broad therapeutic window, which may allow us to achieve high exposures in our early clinical development, thereby achieving maximal NLRP3 inhibition. We expect to submit an IND application for VTX2735 in the second half of 2021 and, if accepted, initiate a Phase 1 clinical trial in healthy volunteers.

Background on Inflammasomes

Inflammasomes are multi-protein signaling complexes that control the inflammatory response and coordinate antimicrobial host defenses. They are activated by a range of pathogen-derived or environmental signals. Detection of these stimuli triggers formation of a large cytoplasmic multimolecular complex that serves to activate caspase 1. Upon activation, caspase 1 cleaves inactive pro-IL-1β into IL-1β. It also cleaves other IL-1 family cytokines, converting inert pro-IL-18 to active IL-18. Caspase 1 also can initiate a cell death process, called pyroptosis, that rapidly releases inflammatory mediators, including, but not limited to, mature IL-1b and IL-18 (Figure 14). These inflammatory mediators recruit additional immune cells that are important to eradicate the infection or cellular injury. However, this feed forward loop, when dysregulated, also forms the basis of many auto-inflammatory diseases.

Figure 14: Role of inflammasomes



Rationale for Targeting NLRP3

NLRP3 is known to be activated by a range of non-infectious tissue damage signals associated with injury, aging, physical inactivity and obesity. When activated, NLRP3 initiates immune responses and stimulates production of inflammatory cytokines IL-1β and IL-18, as well as pyroptosis. Based on both animal model studies and clinical data, NLRP3 has been shown to be associated with a diverse range of diseases and conditions and is thought to be an important contributor to four broad categories of inflammatory disease:

1. Genetic NLRP3-dependent auto-inflammatory diseases, such as CAPS and related conditions, such as familial cold auto-inflammatory syndrome (FCAS), Muckle–Wells syndrome (MWS) and neonatal onset multi-system inflammatory disease (NOMID);
2. Metabolic dysfunction-driven diseases, including non-alcoholic fatty liver disease and non-alcoholic steatohepatitis (NASH), obesity-induced inflammation and type-2 diabetes;
3. Crystal or aggregate formation-associated diseases, including atherosclerosis (cholesterol crystals), gout (monosodium urate crystals), Alzheimer's disease (amyloid-b), Parkinson's disease (a-synuclein) and amyotrophic lateral sclerosis (protein aggregates); and
4. Fibrosis following either acute tissue injury (myocardial infarction) or chronic inflammation (scleroderma, NASH).

While the NLRP3 inflammasome historically has been a challenging drug target, the therapeutic potential of NLRP3 inhibitors in autoimmune disease has been validated by clinical and preclinical data and genetic evidence generated by third parties. Several clinical therapies targeting NLRP3-dependent cytokine anti-IL-1β have been approved, providing validation for its role in a broad range of inflammatory disorders. Approved

therapies include Ilaris (canakinumab) for the treatment of Still's disease and multiple periodic fever syndromes, Kineret (anakinra) for the treatment of Neonatal onset multisystem inflammatory disease (NOMID), and Arcalyst (rilonacept) for the treatment of CAPS. However, the therapeutic window of these drugs is limited by an increased risk of serious infections.

An NLRP3 inhibitor may be less immunosuppressive and better tolerated than an anti-IL-1β therapy because (a) other pathogen-recognizing inflammasomes can be engaged to produce IL-1β, and (b) risk of infection may be lower as the effects of a small molecule therapy are easily reversible upon discontinuation of therapy (hours to days) compared to an antibody, which clears the body very slowly (days to weeks).

In addition, preclinical data has linked NLRP3 activation to over 20 diseases resulting from aberrant inflammation. The most widely used NLRP3 inhibitor reference molecule, MCC950, which has been the starting point for a number of drug discovery programs, suggests efficacy in a wide range of murine disease models that are NLRP3-dependent. Moreover, NLRP3 has been shown to be over-expressed and activated in tissues from patients suffering from a wide range of inflammatory diseases. Finally, gain-of-function mutations in the NLRP3 gene are associated with orphan inflammatory diseases, including CAPS, providing a genetic rationale for NLRP3 inhibition.

Our Solution: VTX2735

VTX2735 is a potent, oral and highly selective small molecule inhibitor of NLRP3 that is peripherally restricted and designed for the treatment of systemic inflammatory diseases, such as cardiovascular, hepatic, renal and rheumatic diseases.

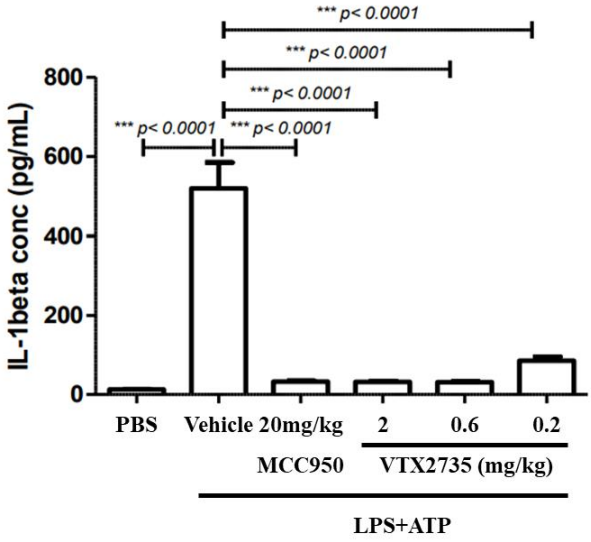
VTX2735 inhibits NLRP3 with an IC_{50} of 48 nM in human whole blood as assessed via lipopolysaccharide (LPS)- and adenosine triphosphate (ATP)-induced IL-1b production. The *in vitro* potency of VTX2735 is approximately ten times greater than first-generation NLRP3 inhibitors, such as MCC950 (Table 5). VTX2735 demonstrated potent *in vitro* activity and dose-dependent reductions of IL-1b release in cells from patients with CAPS, a rare inflammatory autoimmune disease characterized by activating NLRP3 mutations.

Table 5: Head-to-head comparison of *in vitro* potency of VTX2735 and MCC950 (Ventyx data)

IL-1β IC50	VTX2735	MCC950
Mouse Bone Marrow-Derived Macrophages	4 nM	18 nM
Human Monocytes	2 nM	9 nM
Human Whole Blood	48 nM	407 nM
CAPS Patient Monocytes	14-166 nM	>10000 nM

Consistent with potent NLRP3 inhibition, VTX2735 reduced blood IL-1b levels by 90% in an acute mouse model of LPS/ATP challenge. VTX2735 was dosed orally to C57BL/6J mice at 0.2, 0.6 or 2 mg/kg. In addition to a vehicle control group, literature compound MCC-950 was administered at 50 mg/kg as a comparator to a separate group of mice. One hour after compound dosing, mice received 1µg/mouse LPS by intraperitoneal injection, with the exception of the control group, which received phosphate buffered saline (PBS) injection instead. Two hours after LPS injection, all groups, except for the control group, received 0.5 mL of 5 mM ATP. Serum was collected 1 hour after ATP injection and analyzed for IL-1β concentration. As shown below, all animals dosed with NLRP3 inhibitors (MCC950 or VTX2735) inhibited the increase of serum IL-1β to similar levels as seen in mice without challenge. VTX2735 showed dose-dependent inhibition, consistent with an NLRP3-mediated mechanism of action. Notably, VTX2735 reduced blood IL-1β levels by 90% at doses as low as 0.6 mg/kg. This anti-inflammatory activity was achieved at a drug concentration approximately 30 times lower than the dose commonly reported in the literature for NLRP3 reference inhibitor MCC950 used in the study to achieve similar activity.

Figure 15: Effects of VTX2735 in a mouse model of LPS/ATP-stimulated IL-1β release



The PK profile of VTX2735 in rats, dogs and non-human primates (NHPs) supports oral dosing (Table 6). In cynomolgus monkey PK studies, VTX2735 has been shown to be well absorbed with high exposure with approximately 80% bioavailability when administered as an oral solution (Table 6).

Table 6: PK parameters for VTX2735 in preclinical species

PK PARAMETERS	DOSE (ROUTE)	T1/2 (hr)	CL (mL/min/kg)	CMAX (ng/mL)	AUC (ng*hr/mL)	%F
Rat	2 mg/kg (IV)	4.2	5.6	7590	6113	—
	5 mg/kg (PO)	4.8	—	1,037	6,374	42
Dog	2 mg/kg (IV)	3.7	20	4,795	1,674	—
	5 mg/kg (PO)	5.2	—	2,060	3,651	85
Monkey	1 mg/kg (IV)	3.3	1.6	15,265	10,413	—
	5 mg/kg (PO)	4.1	—	16,867	41,800	80

In summary, VTX2735 had high NLRP3 inhibition potency both *in vitro* and *in vivo* as measured by IL-1b lowering ability in cellular assays and animal models, good oral bioavailability, and an attractive *in vivo/in vitro* safety profile based on preclinical safety assessment. Based on the toxicokinetic (TK) exposures attained in GLP toxicology studies, we expect a safety margin >100-fold based on human whole blood IL-1β IC_{50} values for VTX2735.

Clinical Development Plan for VTX2735

IND-enabling studies for VTX2735 currently are underway. We expect to submit an IND application for VTX2735 in the second half of 2021 and, if accepted, initiate a Phase 1 clinical trial in healthy volunteers. Pending our Phase 1 results, we expect to initiate a Phase 2a POC trial, which will be supported by *ex vivo* whole blood stimulation assays for PD. We currently are evaluating potential indications for our POC trials based on relevance of NLRP3 dysregulation.

Competition and Differentiation for VTX2735

Although there are no approved NLRP3 inhibitor therapies currently, several molecules are in development for treatment of inflammatory diseases, including DFV890 from Novartis (Phase 2 for COVID-19 pneumonia completed); Inzomelid and Somalix from Roche AG (Phase 1 completed); NT-0167 (Phase 1 ongoing) and NT-

0796 (pre-clinical) from NodThera; and OLT-1177 (Phase 2 for Schnitzler Syndrome and COVID-19 ongoing) from Olatec Therapeutics LLC.

VTX2735 is differentiated from these other NLRP3 inhibitors due to its potency and selectivity in human whole blood assays, potency against activating mutations, robust pharmacodynamic activity in human cells, and potent dose-dependent activity in animal models.

Expanding our NLRP3 portfolio: CNS- and Tissue-Specific Inhibitors

In addition to our peripheral NLRP3 inhibitor VTX2735 for systemic conditions, our portfolio of NLRP3 compounds includes CNS-penetrant compounds and tissue-specific inhibitors for localized inflammatory diseases, such as in skin, GI tract and lung.

- The CNS-penetrant compounds have potential therapeutic utility for the treatment of Alzheimer's disease, Parkinson's disease, amyotrophic lateral sclerosis, and MS, based on preclinical and clinical evidence underscoring the pathogenic role of NLRP3 in these neurodegenerative diseases; and
- The tissue-specific NLRP3 inhibitors are designed to have no systemic exposure or biological activity. Based on the route of administration—topical, oral or inhaled—there is the potential to selectively target NLRP3-dependent diseases in the skin, GI tract and lung, respectively.

Competition

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. While we believe that our scientific knowledge, technology and development experience provide us with competitive advantages, we face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions. Any therapeutic candidates that we successfully develop and commercialize will compete with existing products and new products that may become available in the future.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industry may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize therapeutic products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic products. If our product candidates achieve marketing approval, we expect that they will be priced at a significant premium over competitive products.

The key competitive factors affecting the success of all of our therapeutic product candidates, if approved, are likely to be efficacy, safety, convenience, price, the level of competition, intellectual property protection and the availability of reimbursement from government and other third-party payors.

We expect to face competition from existing products and products in development for each of our product candidates.

Our success will be based in part on our ability to identify, develop and commercialize a portfolio of product candidates that have a lower risk of side effects and/or provide more symptomatic improvement than competing products.

In addition to specific competitors described below, there may be other early stage or pre-clinical programs that, if approved, would compete with our product candidates. Many of our competitors have substantially greater financial, technical and human resources than we have. Additional mergers and acquisitions in the

pharmaceutical industry may result in even more resources being concentrated in our competitors. Competition may increase further as a result of advances made in the commercial applicability of technologies and greater availability of capital for investment in these fields. Our success will be based in part on our ability to build and actively manage a portfolio of drugs that addresses unmet medical needs and creates value in patient therapy.

VTX958 (Psoriasis)

VTX958, currently in development for the treatment of moderate-to-severe psoriasis, is an oral TYK2 inhibitor, a class of medicines with no currently approved agents. If approved for the treatment of patients with moderate-to-severe psoriasis, VTX958 would compete with injected biologic therapies, such as Humira and Skyrizi, marketed by AbbVie Inc. and Eisai Co., Ltd., Stelara and Tremfya, marketed by Johnson & Johnson, Taltz, marketed by Eli Lilly and Company, Cosentyx, marketed by Novartis AG, Siliq, marketed by Bausch Health Companies, Inc., and Enbrel, marketed by Amgen Inc., Pfizer Inc. and Takeda Pharmaceutical Company Limited; non-injectable systemic therapies used to treat plaque psoriasis, such as Otezla, marketed by Amgen Inc.; topical therapies, such as branded and generic versions of clobetasol, such as Clobex, marketed by Galderma Laboratories, LP, generic versions of calcipotriene and the combination of betamethasone dipropionate/calcipotriene; and other treatments, including various lasers and ultraviolet light-based therapies.

We are aware of several companies with product candidates in development for the treatment of patients with psoriasis, including tapinarof, which is a natural AhR agonist being developed by Dermavant Sciences, Inc.; deucravacitinib, which is an oral TYK2 inhibitor being developed by BMS; PF-06700841, which is a TYK2/JAK1 inhibitor being developed by Pfizer, Inc.; and GLPG3667, which is a TYK2/JAK1 inhibitor being developed by Galapagos N.V. In addition to deucravacitinib, we are aware of three other Phase 1 clinical stage allosteric TYK2 inhibitors, including BMS' BMS-986322 (a follow-on molecule to deucravacitinib), an undisclosed lead compound from Nimbus Therapeutics, Inc. (currently partnered with BMS) and Esker Therapeutics, Inc.'s ESK-001.

VTX002 (Ulcerative Colitis)

VTX002, currently in development for the treatment of moderate-to-severe UC, is an oral S1P1R modulator. If approved for the treatment of patients with moderate-to-severe UC, VTX002 would compete with: Zeposia (ozanimod), which is an S1P1R modulator marketed by BMS; Entyvio (vedolizumab), which is an α4β7 integrin antibody marketed by Takeda; Humira (adalimumab), which is a TNF antibody marketed by AbbVie Inc.; Stelara (ustekinumab), which is an IL-12/IL-23 antibody marketed by Johnson & Johnson; Xeljanz (tofacitinib), which is a JAK1 inhibitor marketed by Pfizer Inc.; and Simponi (golimumab), which is a TNF antibody marketed by Johnson & Johnson.

We are aware of several companies with product candidates in development for the treatment of patients with UC, including: etrasimod, which is an S1PR modulator being developed in Phase 3 clinical trials by Arena Pharmaceuticals, Inc.; Pfizer Inc.'s PF-06480605, a Phase 2 TNFSF15 blocker; upadacitinib, which is a JAK1 inhibitor being developed in Phase 3 clinical trials by AbbVie Inc.; risankizumab, guselkumab and mirikizumab, which are anti-IL-23 antibodies being developed in Phase 3 clinical trials by Abbvie, Inc., Janssen Pharmaceuticals N.V. and Eli Lilly and Company, respectively; and Jyseleca (filgotinib), a JAK1 inhibitor being developed in Phase 3 clinical trials by Gilead Sciences, Inc. and Galapagos N.V. We are also aware of additional product candidates in clinical trials by AbbVie Inc., Abivax SA, Amgen Inc., Bausch Health Companies, Inc. (Salix Pharmaceuticals), BMS, Connect Biopharma Holdings Limited, Gilead Sciences, Inc., GlaxoSmithKline plc, Gossamer Bio, Inc., I-Mab Biopharma Co. Ltd., Incyte Corp., Janssen Pharmaceuticals N.V., Landos Biopharma, Inc., Morphic Therapeutic, Inc., Pfizer Inc., Prometheus Biosciences, Inc., Protagonist Therapeutics, Inc., Theravance Biopharma, Inc., Applied Molecular Transport Inc., Pandion Therapeutics, Inc., RedHill Biopharma Ltd. and Seres Therapeutics, Inc.

VTX2735 (NLRP3 Inhibitor)

VTX2735 is our preclinical NLRP3 inhibitor product candidate, a class of medicines with no currently approved agents. We expect to submit an IND application for VTX2735 in the second half of 2021 and if accepted, initiate a Phase 1 clinical trial in healthy volunteers. We are aware of several other NLRP3 inhibitors in clinical or preclinical development, including Inzomelid and Somalix being developed by Roche AG; DFV890 being developed by Novartis; NT-0167 being developed by Nodthera; OLT1177 being developed by Olatec Therapeutics LLC; and an undisclosed preclinical stage compound from Ventus Therapeutics, Inc.

Manufacturing

We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We rely on third-party manufacturers for the manufacture of our product candidates for preclinical and clinical testing. We

intend to rely on third-party contract manufacturers for commercial manufacturing if our product candidates receive marketing approval. We believe there are multiple sources for all of the materials required for the manufacture of our product candidates. Our manufacturing strategy enables us to more efficiently direct financial resources to the research, development and commercialization of product candidates rather than diverting resources to internally develop manufacturing facilities. As our product candidates advance through development, we expect to enter into longer-term commercial supply agreements with key suppliers and manufacturers to fulfill and secure our production needs.

Intellectual Property

We strive to protect the proprietary technology, inventions and improvements that are commercially important to our business, including seeking, maintaining and defending patent rights, whether developed internally or licensed from third parties. Our policy is to seek to protect our proprietary position by, among other methods, filing patent applications in the U.S. and in jurisdictions outside of the U.S. directed to our proprietary technology, inventions, improvements and product candidates that are important to the development and implementation of our business. We also rely on trade secrets and know-how relating to our proprietary technology and product candidates and continuing innovation to develop, strengthen and maintain our proprietary position. We also plan to rely on data exclusivity, market exclusivity and patent term extensions when available. Our commercial success will depend in part on our ability to obtain and maintain patent and other proprietary protection for our technology, inventions and improvements; to preserve the confidentiality of our trade secrets; to defend and enforce our proprietary rights, including any patents that we may own in the future; and to operate without infringing on the valid and enforceable patents and other proprietary rights of third parties.

VTX958

As of August 3, 2021, with respect to our TYK2 program, we own one pending U.S. patent application, two pending foreign patent applications and three international patent applications filed under the Patent Cooperation Treaty, or PCT. More specifically, we own one pending U.S. patent application, two pending foreign patent applications and one pending international patent applications filed under the PCT with claims directed to our lead product candidate, VTX958, and other related compounds as a composition of matter, as well as claims directed to pharmaceutical compositions and uses of such compounds, including the use of VTX958, to treat inflammatory or autoimmune diseases, including psoriasis. Any patents that may issue from these pending applications are expected to expire in November 2040, absent any patent term adjustments or extensions.

VTX002

As of August 3, 2021, with respect to our S1P1R program, we own one U.S. patent, one pending U.S. patent application, two foreign patents and eleven pending foreign patent applications with claims directed to our lead product candidate, VTX002, and other related compounds as a composition of matter, as well as claims directed to pharmaceutical compositions and uses of such compounds, including the use of VTX002, to treat UC. The issued patents, and any patents that may issue from these pending applications, are expected to expire in November 2036 absent any patent term adjustments or extensions.

VTX2735

As of August 3, 2021, with respect to our NLRP3 program, we own one pending U.S. patent application, one pending U.S. provisional patent application, two pending foreign patent applications and three international patent applications filed under the Patent Cooperation Treaty, or PCT. More specifically, we own one pending U.S. patent application, two pending foreign patent applications and one international patent applications filed under the PCT with claims directed to our lead product candidate, VTX2735, and other related compounds as a composition of matter, as well as claims directed to pharmaceutical compositions and uses of such compounds, including VTX2735. Any patents that may issue from these pending applications are expected to expire in March 2041, absent any patent term adjustments or extensions.

We also possess know-how and trade secrets relating to the development and commercialization of our product candidates.

With respect to our product candidates and processes we intend to develop and commercialize in the normal course of business, we intend to pursue patent protection covering, when possible, compositions, methods of use, dosing and formulations. We may also pursue patent protection with respect to manufacturing and drug development processes and technologies.

Issued patents can provide protection for varying periods of time, depending upon the date of filing of the patent application, the date of patent issuance and the legal term of patents in the countries in which they are obtained. In general, patents issued for applications filed in the U.S. can provide exclusionary rights for 20 years from the earliest effective filing date. In addition, in certain instances, the term of an issued U.S. patent that covers or claims an FDA approved product can be extended to recapture a portion of the term effectively lost as a result of the FDA regulatory review period, which is called patent term extension. The restoration period cannot be longer than five years and the total patent term, including the restoration period, must not exceed 14 years following FDA approval. The term of patents outside of the U.S. varies in accordance with the laws of the foreign jurisdiction, but typically is also 20 years from the earliest effective filing date. However, the actual protection afforded by a patent varies on a product-by-product basis, from country-to-country, and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patent.

The patent positions of companies like ours are generally uncertain and involve complex legal and factual questions. No consistent policy regarding the scope of claims allowable in patents in the field of immunology has emerged in the U.S. The relevant patent laws and their interpretation outside of the U.S. is also uncertain. Changes in either the patent laws or their interpretation in the U.S. and other countries may diminish our ability to protect our technology or product candidates and could affect the value of such intellectual property. In particular, our ability to stop third parties from making, using, selling, offering to sell or importing products that infringe our intellectual property will depend in part on our success in obtaining and enforcing patent claims that cover our technology, inventions and improvements. We cannot guarantee that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications we may file in the future, nor can we be sure that any patents that may be granted to us in the future will be commercially useful in protecting our products, the methods of use or manufacture of those products. Moreover, even our issued patents do not guarantee us the right to practice our technology in relation to the commercialization of our products. Patent and other intellectual property rights in the pharmaceutical and biotechnology space are evolving and involve many risks and uncertainties. For example, third parties may have blocking patents that could be used to prevent us from commercializing our product candidates and practicing our proprietary technology, and our issued patents may be challenged, invalidated or circumvented, which could limit our ability to stop competitors from marketing related products or could limit the term of patent protection that otherwise may exist for our product candidates. In addition, the scope of the rights granted under any issued patents may not provide us with protection or competitive advantages against competitors with similar technology. Furthermore, our competitors may independently develop similar technologies that are outside the scope of the rights granted under any issued patents. For these reasons, we may face competition with respect to our product candidates. Moreover, because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any particular product candidate can be commercialized, any patent protection for such product may expire or remain in force for only a short period following commercialization, thereby reducing the commercial advantage the patent provides.

Government Regulation

Government authorities in the U.S., at the federal, state and local level, and other countries extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, marketing and export and import of products such as those we are developing. A new drug must be approved by the FDA through the new drug application, or NDA, process before it may be legally marketed in the U.S.

U.S. Drug Development Process

In the U.S., the FDA regulates drugs, including small molecules, under the federal Food, Drug, and Cosmetic Act, or the FDCA, and its implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval may subject an applicant to administrative or judicial sanctions. These sanctions could include the FDA's refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

The process required by the FDA before a drug may be marketed in the U.S. generally involves the following:

- completion of preclinical laboratory tests, animal studies and formulation studies in accordance with Good Laboratory Practice, or GLP, regulations and other applicable regulations;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- approval by an independent institutional review board, or IRB, at each clinical site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with Good Clinical Practice, or GCP, regulations to establish the safety and efficacy of the proposed drug for its intended use;
- submission to the FDA of an NDA;
- a determination by the FDA within 60 days of its receipt of an NDA to accept the filing for review;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with current GMP, or cGMP, requirements to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity; and
- satisfactory completion of other studies required by the FDA, including immunogenicity, carcinogenicity, genotoxicity and stability studies;
- FDA review and approval of the NDA to permit commercial marketing of the product for particular indications for use in the U.S.; and
- compliance with any post-approval requirements, including the potential requirement to implement a REMS, and the potential requirement to conduct post-approval studies.

Once a pharmaceutical candidate is identified for development, it enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information and analytical data, to the FDA as part of the IND. An IND is a request for authorization from the FDA to administer an investigational new drug product to humans. The sponsor will also include a protocol detailing, among other things, the objectives of the first phase of the clinical trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated, if the first phase lends itself to an efficacy evaluation. Some preclinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, places the clinical trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Clinical holds also may be imposed by the FDA at any time before or during clinical trials due to safety concerns about on-going or proposed clinical trials or non-compliance with specific FDA requirements, and the trials may not begin or continue until the FDA notifies the sponsor that the hold has been lifted. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial.

All clinical trials must be conducted under the supervision of one or more qualified investigators in accordance with GCP regulations, which include the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial. They must be conducted under protocols detailing, among other things, the objectives of the trial, dosing procedures, subject selection and exclusion criteria and the safety and effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND as well as any subsequent protocol amendments, and timely safety reports must be submitted to the FDA and the investigators for serious and unexpected adverse events. An IRB at each institution participating in the clinical trial must review and approve each protocol before a clinical trial commences at that institution and must also approve the information regarding the trial and the consent form that must be provided to each trial subject or his or her legal representative, monitor the study until completed and otherwise comply with IRB regulations.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- *Phase 1*: The product candidate is initially introduced into healthy human volunteers and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion and, if possible, to gain an early indication of its effectiveness. In the case of some products for severe or life-threatening diseases, such as cancer, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients. Sponsors sometimes designate their Phase 1 clinical trials as Phase 1a or Phase 1b. Phase 1b clinical trials are

typically aimed at confirming dosing, pharmacokinetics and safety in larger number of patients. Some Phase 1b studies evaluate biomarkers or surrogate markers that may be associated with efficacy in patients with specific types of diseases.

- *Phase 2*: This phase involves clinical trials in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and appropriate dosage.
- *Phase 3*: Clinical trials are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population, generally at geographically dispersed clinical study sites. These clinical trials are intended to establish the overall risk-benefit ratio of the product candidate and provide, if appropriate, an adequate basis for product labeling.

Post-approval trials, sometimes referred to as Phase 4 studies, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA.

The FDA or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. In addition, some clinical trials are overseen by an independent group of qualified experts organized by the sponsor, known as a data safety monitoring board or committee. Depending on its charter, this group may determine whether a trial may move forward at designated check points based on access to certain data from the trial.

During the development of a new drug, sponsors are given opportunities to meet with the FDA at certain points. These points may be prior to submission of an IND, at the end of Phase 2, and before an NDA is submitted. Meetings at other times may be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for the FDA to provide advice, and for the sponsor and the FDA to reach agreement on the next phase of development. Sponsors typically use the meetings at the end of the Phase 2 trial to discuss Phase 2 clinical results and present plans for the pivotal Phase 3 clinical trials that they believe will support approval of the new drug.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final drug. In addition, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

While the IND is active and before approval, progress reports summarizing the results of the clinical trials and nonclinical studies performed since the last progress report must be submitted at least annually to the FDA, and written IND safety reports must be submitted to the FDA and investigators for serious and unexpected suspected adverse events, findings from other studies suggesting a significant risk to humans exposed to the same or similar drugs, findings from animal or *in vitro* testing suggesting a significant risk to humans, and any clinically important increased incidence of a serious suspected adverse reaction compared to that listed in the protocol or investigator brochure.

There are also requirements governing the reporting of ongoing clinical trials and completed trial results to public registries. Sponsors of certain clinical trials of FDA-regulated products are required to register and disclose specified clinical trial information, which is publicly available at www.clinicaltrials.gov. Information related to the product, patient population, phase of investigation, trial sites and investigators and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to discuss the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed until the new product or new indication being studied has been approved.

As a result of the COVID-19 public health emergency, we may be required to develop and implement additional clinical trial policies and procedures designed to help protect subjects from the COVID-19 virus. For example, in March 2020, the FDA issued a guidance, which the FDA subsequently updated, on conducting clinical trials

during the pandemic. In June 2020, FDA also issued a guidance on good manufacturing practice considerations for responding to COVID-19 infection in employees in drug products manufacturing, including recommendations for manufacturing controls to prevent contamination of drugs. Additional COVID-19 related guidance released by FDA include guidance addressing resuming normal drug and biologics manufacturing operations; manufacturing, supply chain, and inspections; and statistical considerations for clinical trials during the COVID-19 public health emergency. In view of the spread of the COVID-19 variants, FDA may issue additional guidance and policies that may materially impact our business and clinical development timelines. The ultimate impact of the COVID-19 pandemic on our business operations and clinical development plans is highly uncertain and subject to change and will depend on future developments, including new regulatory requirements and changes to existing regulations. If new guidance and policies are promulgated by the FDA that require changes in our clinical protocol or clinical development plans, our anticipated timelines and regulatory approval may be delayed or materially impacted.

NDA Review and Approval Process

The results of product development, preclinical and other non-clinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the drug, proposed labeling and other relevant information are submitted to the FDA as part of an NDA requesting approval to market the product. The submission of an NDA is subject to the payment of substantial user fees; a waiver of such fees may be obtained under certain limited circumstances. The FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use and whether its manufacturing is cGMP-compliant to assure and preserve the product's identity, strength, quality and purity. Under the Prescription Drug User Fee Act, or PDUFA, guidelines that are currently in effect, the FDA has a goal of ten months from the date of "filing" of a standard NDA for a new molecular entity to review and act on the submission. This review typically takes twelve months from the date the NDA is submitted to FDA because the FDA has approximately two months to make a "filing" decision after it the application is submitted. The FDA conducts a preliminary review of all NDAs within the first 60 days after submission, before accepting them for filing, to determine whether they are sufficiently complete to permit substantive review The FDA may request additional information rather than accept an NDA for filing. In this event, the NDA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing.

The FDA may refer an application for a novel drug to an advisory committee. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. Before approving an NDA, the FDA will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA may inspect one or more clinical trial sites to assure compliance with GCP requirements.

After the FDA evaluates an NDA, it will issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete and the application will not be approved in its present form. A Complete Response Letter usually describes the specific deficiencies in the NDA identified by the FDA and may require additional clinical data, such as an additional pivotal Phase 3 trial or other significant and time consuming requirements related to clinical trials, nonclinical studies or manufacturing. If a Complete Response Letter is issued, the sponsor must resubmit the NDA or, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if such data and information are submitted, the FDA may decide that the NDA does not satisfy the criteria for approval.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. In addition, the FDA may require a sponsor to conduct Phase 4 testing, which involves clinical trials designed to further assess a drug's safety and effectiveness after NDA approval, and may require testing and surveillance programs to monitor the safety of approved products which have been commercialized. The FDA may also place other conditions on approval including the requirement for a risk evaluation and mitigation strategy, or REMS, to assure the safe use of the drug. If the FDA concludes a REMS is needed, the sponsor of the NDA must submit a proposed REMS. The FDA will not approve the NDA without an approved REMS, if required. A REMS could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these

limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Marketing approval may be withdrawn for non-compliance with regulatory requirements or if problems occur following initial marketing.

The Pediatric Research Equity Act, or PREA, requires a sponsor to conduct pediatric clinical trials for most drugs, for a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration. Under PREA, original NDAs and supplements must contain a pediatric assessment unless the sponsor has received a deferral or waiver. The required assessment must evaluate the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The sponsor or FDA may request a deferral of pediatric clinical trials for some or all of the pediatric subpopulations. A deferral may be granted for several reasons, including a finding that the drug is ready for approval for use in adults before pediatric clinical trials are complete or that additional safety or effectiveness data needs to be collected before the pediatric clinical trials begin. The FDA must send a non-compliance letter to any sponsor that fails to submit the required assessment, keep a deferral current or fails to submit a request for approval of a pediatric formulation.

Expedited Development and Review Programs

A sponsor may seek approval of its product candidate under programs designed to accelerate FDA's review and approval of new drugs and biological products that meet certain criteria. The FDA has a fast track designation program that is intended to expedite or facilitate the process for reviewing new drug products that meet certain criteria. Specifically, new drugs are eligible for Fast Track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Unique to a fast track product, the FDA may consider for review sections of the NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA.

Any product submitted to the FDA for approval, including a product with a fast track designation, may also be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. A product is eligible for priority review if it has the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or a significant improvement in the safety or effectiveness of the treatment, diagnosis or prevention of a serious disease or condition. The FDA will attempt to direct additional resources to the evaluation of an application for a new drug designated for priority review in an effort to facilitate the review. The FDA endeavors to review applications with priority review designations within six months of the filing date as compared to ten months for review of new molecular entity NDAs under its current PDUFA review goals. Priority review designation does not change the scientific/medical standard for approval or the quality of evidence necessary to support approval.

In addition, a product may be eligible for accelerated approval. Drug products intended to treat serious or life-threatening diseases or conditions may be eligible for accelerated approval upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require that a sponsor of a drug receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product. FDA may withdraw approval of a drug or indication approved under accelerated approval if, for example, the confirmatory trial fails to verify the predicted clinical benefit of the product.

A sponsor may seek FDA designation of a product candidate as a "breakthrough therapy" if the product is intended, alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. If the FDA designates a breakthrough therapy, it may take actions appropriate to expedite the development and review of the application, which may include holding meetings with the sponsor and the review team throughout the development of the therapy; providing timely advice to, and interactive communication with, the sponsor regarding the development of the drug to ensure

that the development program to gather the nonclinical and clinical data necessary for approval is as efficient as practicable; involving senior managers and experienced review staff, as appropriate, in a collaborative, cross-disciplinary review; assigning a cross-disciplinary project lead for the FDA review team to facilitate an efficient review of the development program and to serve as a scientific liaison between the review team and the sponsor; and considering alternative clinical trial designs when scientifically appropriate, which may result in smaller trials or more efficient trials that require less time to complete and may minimize the number of patients exposed to a potentially less efficacious treatment. The designation includes all of the fast track program features, which means that the sponsor may file sections of the NDA for review on a rolling basis if certain conditions are satisfied, including an agreement with FDA on the proposed schedule for submission of portions of the application and the payment of applicable user fees before the FDA may initiate a review. The breakthrough therapy designation is a distinct status from both accelerated approval and priority review, which can also be granted to the same drug if relevant criteria are met. If a product is designated as breakthrough therapy, the FDA will work to expedite the development and review of such drug.

Fast track designation, priority review and breakthrough therapy designation do not change the standards for approval but may expedite the development or approval process. Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. We may explore some of these opportunities for our product candidates as appropriate. Depending on other factors that impact clinical trial timelines and development, such as our ability to identify and onboard clinical sites and rates of study participant enrollment and drop-out, we may not realize all the benefits of these expedited or accelerated review programs.

Post-Approval Requirements

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market. After approval, some types of changes to the approved product, such as adding new indications, certain manufacturing changes and additional labeling claims, are subject to further FDA review and approval. Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP regulations and other laws and regulations. In addition, the FDA may impose a number of post-approval requirements as a condition of approval of an NDA. For example, the FDA may require post-marketing testing, including Phase 4 clinical trials, and surveillance to further assess and monitor the product's safety and effectiveness after commercialization.

Any drug products manufactured or distributed by us or our partners pursuant to FDA approvals will be subject to pervasive and continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse experiences with the drug, providing the FDA with updated safety and efficacy information, drug sampling and distribution requirements, complying with certain electronic records and signature requirements and complying with FDA promotion and advertising requirements. The FDA strictly regulates labeling, advertising, promotion and other types of information on products that are placed on the market and imposes requirements and restrictions on drug manufacturers, such as those related to direct-to-consumer advertising, the prohibition on promoting products for uses or in patient populations that are not described in the product's approved labeling (known as "off-label use"), industry-sponsored scientific and educational activities and promotional activities involving the internet.

Discovery of previously unknown problems or the failure to comply with the applicable regulatory requirements may result in restrictions on the marketing of a product or withdrawal of the product from the market as well as possible civil or criminal sanctions. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant or manufacturer to administrative or judicial civil or criminal sanctions and adverse publicity. FDA sanctions could include refusal to approve pending applications, withdrawal of an approval, clinical holds on post-approval clinical trials, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, mandated corrective advertising or communications with doctors, debarment, restitution, disgorgement of profits, or civil or criminal penalties.

NDA Marketing Exclusivity

Market exclusivity provisions under the FDCA can delay the submission or the approval of certain marketing applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the U.S. to the first applicant to obtain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not approve or even accept for review an abbreviated new drug application, or ANDA, or an NDA submitted under Section 505(b)(2), or 505(b)(2) NDA, submitted by another company for another drug based on the same active moiety, regardless of whether the drug is intended for the same indication as the original innovative drug or for another indication, where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement to one of the patents listed with the FDA by the innovator NDA holder.

The FDCA alternatively provides three years of marketing exclusivity for an NDA, or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the modification for which the drug received approval on the basis of the new clinical investigations and does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs for drugs containing the active agent for the original indication or condition of use. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Pediatric exclusivity is another type of marketing exclusivity available in the U.S. Pediatric exclusivity provides for an additional six months of marketing exclusivity attached to another period of exclusivity if a sponsor conducts clinical trials in children in response to a written request from the FDA. The issuance of a written request does not require the sponsor to undertake the described clinical trials. In addition, orphan drug exclusivity, as described above, may offer a seven-year period of marketing exclusivity, except in certain circumstances.

U.S. Coverage and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidate for which we may seek regulatory approval. Sales in the U.S. will depend, in part, on the availability of sufficient coverage and adequate reimbursement from third-party payors, which include government health programs such as Medicare, Medicaid, TRICARE and the Veterans Administration, as well as managed care organizations and private health insurers. Prices at which we or our customers seek reimbursement for our product candidates can be subject to challenge, reduction or denial by third-party payors.

The process for determining whether a third-party payor will provide coverage for a product is typically separate from the process for setting the reimbursement rate that the payor will pay for the product. A third-party payor’s decision to provide coverage for a product does not imply that an adequate reimbursement rate will be available. Additionally, in the U.S. there is no uniform policy among payors for coverage or reimbursement. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies, but also have their own methods and approval processes. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. If coverage and adequate reimbursement are not available, or are available only at limited levels, successful commercialization of, and obtaining a satisfactory financial return on, any product we develop may not be possible.

Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. In order to obtain coverage and reimbursement for any product that might be approved for marketing, we may need to conduct expensive studies in order to demonstrate the medical necessity and cost-effectiveness of any products, which would be in addition to the costs expended to obtain regulatory approvals. Third-party payors may not consider our product candidates to be medically necessary or cost-effective compared to other available therapies, or the rebate percentages required to secure favorable coverage may not yield an adequate margin over cost or may not enable us to maintain price levels sufficient to realize an appropriate return on our investment in drug development.

U.S. Healthcare Reform

In the U.S., there has been, and continues to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities and affect the profitable sale of product candidates.

Among policy makers and payors in the U.S., there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the U.S., the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the ACA, was passed, which substantially changed the way healthcare is financed by both the government and private insurers, and significantly impacts the U.S. pharmaceutical industry. The ACA, among other things: (1) increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations; (2) created a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for certain drugs and biologics that are inhaled, infused, instilled, implanted or injected; (3) established an annual, nondeductible fee on any entity that manufactures or imports certain specified branded prescription drugs and biologic agents apportioned among these entities according to their market share in certain government healthcare programs; (4) expanded the availability of lower pricing under the 340B drug pricing program by adding new entities to the program; (5) expanded the eligibility criteria for Medicaid programs; (6) created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research; (7) created a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% (and 70% commencing January 1, 2019) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; (8) established a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and (9) established a Center for Medicare Innovation at the Centers for Medicare & Medicaid Services, or CMS, to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drugs.

Since its enactment, there have been executive, judicial and Congressional challenges to certain aspects of the ACA. For example, in June 2021 the U.S. Supreme Court held that Texas and other challengers had no legal standing to challenge the ACA, dismissing the case on procedural grounds without specifically ruling on the constitutionality of the ACA. Thus, the ACA will remain in effect in its current form. Further, prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period in 2021 for purposes of obtaining health insurance coverage through the ACA marketplace, which began on February 15, 2021 and remained open through August 15, 2021. This executive order also instructs certain governmental agencies to review existing policies and rules that limit access to health insurance coverage through Medicaid or the ACA, among others. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges and healthcare measures promulgated by the Biden administration will impact the ACA, our business, financial condition and results of operations. Complying with any new legislation or reversing changes implemented under the ACA could be time-intensive and expensive, resulting in a material adverse effect on our business.

Other legislative changes have been proposed and adopted since the ACA was enacted. On August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, resulted in aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect in 2013 and will remain in effect through 2030, with the exception of a temporary suspension implemented under various COVID-19 relief legislation from May 1, 2020 through the end of 2021, unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Moreover, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. At the federal level, the Trump administration used

several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, in 2020, the U.S. Department of Health and Human Services ("HHS") and the CMS issued various rules that are expected to impact, among others, price reductions from pharmaceutical manufacturers to plan sponsors under Part D, fee arrangements between pharmacy benefit managers and manufacturers, manufacturer price reporting requirements under the Medicaid Drug Rebate Program, including regulations that affect manufacturer-sponsored patient assistance programs subject to pharmacy benefit manager accumulator programs and Best Price reporting related to certain value-based purchasing arrangements. Multiple lawsuits have been brought against the HHS challenging various aspects of the rules. Under the American Rescue Plan Act of 2021, effective January 1, 2024, the statutory cap on Medicaid Drug Rebate Program rebates that manufacturers pay to state Medicaid programs will be eliminated. Elimination of this cap may require pharmaceutical manufacturers to pay more in rebates than it receives on the sale of products, which could have a material impact on our business. Further, based on a recent executive order, the Biden administration expressed its intent to pursue certain policy initiatives to reduce drug prices. Any reduction in reimbursement from Medicare or other government programs may result in a reduction in payments from private payors. The impact of legislative, executive and administrative actions of the Biden administration on us and the pharmaceutical industry as a whole is unclear.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. We are unable to predict the future course of federal or state healthcare legislation in the U.S. directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. Further, it is possible that additional governmental action will be taken in response to the COVID-19 pandemic. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our products candidates may lose regulatory approval that may have been obtained and we may not achieve or sustain profitability.

U.S. Healthcare Fraud and Abuse Laws and Compliance Requirements

Federal and state healthcare laws and regulations restrict business practices in the pharmaceutical industry. These laws include anti-kickback and false claims laws and regulations, data privacy and security and transparency laws and regulations.

The federal Anti-Kickback Statute prohibits, among other things, individuals or entities from knowingly and willfully offering, paying, soliciting or receiving remuneration, directly or indirectly, overtly or covertly, in cash or in kind to induce or in return for purchasing, leasing, ordering or arranging for or recommending the purchase, lease or order of any item or service reimbursable under Medicare, Medicaid or other federal healthcare programs. A person or entity does not need to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act and the Civil Monetary Penalties Statute.

The federal civil and criminal false claims laws and civil monetary penalties laws, including the civil False Claims Act, prohibit, among other things, any individual or entity from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created additional federal civil and criminal statutes that prohibit, among other things, knowingly and willfully executing a scheme to defraud any healthcare benefit program. In addition, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and their implementing regulations, imposes certain requirements relating to the privacy, security and transmission of protected health information on HIPAA covered entities, which include certain healthcare providers, health plans and healthcare clearinghouses, and their business associates who conduct certain activities for or on their behalf involving protected health information on their behalf as well as their covered subcontractors.

The federal Physician Payments Sunshine Act requires applicable group purchasing organizations and applicable manufacturers of covered drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to CMS information related to certain payments or other transfers of value made to covered

recipients, including physicians licensed to practice in the U.S. (defined to include doctors of medicine and osteopathy, dentists, podiatrists, optometrists and licensed chiropractors), and teaching hospitals, in the previous year, including ownership and investment interests held by covered physicians and their immediate family members. Effective January 1, 2021, for data collected in 2021 and submitted to CMS in 2022, such reporting obligations with respect to covered recipients have been extended to include new provider types: physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and anesthesiologist assistants and certified nurse-midwives

Similar state and local laws and regulations may also restrict business practices in the pharmaceutical industry, such as state anti-kickback and false claims laws, which may apply to business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, or by patients themselves; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments or transfers of value that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information or which require tracking gifts and other remuneration and items of value provided to physicians, other healthcare providers and entities; state and local laws that require the registration of pharmaceutical sales representatives; and state and local laws governing the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure compliance with applicable healthcare laws and regulations can involve substantial costs. Violations of healthcare laws can result in significant penalties, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgement, individual imprisonment, possible exclusion from participation in Medicare, Medicaid and other U.S. healthcare programs, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings, and curtailment or restructuring of operations.

Foreign Regulation

In order to market any product outside of the U.S., we would need to comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we would need to obtain the necessary approvals by the comparable foreign regulatory authorities before we can commence clinical trials or marketing of the product in foreign countries and jurisdictions. Although many of the issues discussed above with respect to the U.S. apply similarly in the context of the European Union, or EU, the approval process varies between countries and jurisdictions and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries or jurisdictions might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others.

To market a medicinal product in the European Economic Area, or EEA (which is comprised of the 27 Member States of the EU plus Norway, Iceland and Liechtenstein), we must obtain a Marketing Authorization, or MA. There are two types of marketing authorizations:

- the Community MA, which is issued by the European Commission through the Centralized Procedure, based on the opinion of the Committee for Medicinal Products for Human Use of the European Medicines Agency, or EMA, and which is valid throughout the entire territory of the EEA. The Centralized Procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, advanced therapy products and medicinal products containing a new active substance indicated for the treatment certain diseases, such as AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and viral diseases. The Centralized Procedure is optional for products containing a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU; and
- National MAs, which are issued by the competent authorities of the Member States of the EEA and only cover their respective territory, are available for products not falling within the mandatory scope of the Centralized Procedure. Where a product has already been authorized for marketing in a Member

State of the EEA, this National MA can be recognized in another Member State through the Mutual Recognition Procedure. If the product has not received a National MA in any Member State at the time of application, it can be approved simultaneously in various Member States through the Decentralized Procedure.

Under the above described procedures, before granting the MA, the EMA or the competent authorities of the Member States of the EEA make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

Data and Marketing Exclusivity

In the EEA, new products authorized for marketing, or reference products, qualify for eight years of data exclusivity and an additional two years of market exclusivity upon marketing authorization. The data exclusivity period prevents generic or biosimilar applicants from relying on the preclinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar marketing authorization in the EU during a period of eight years from the date on which the reference product was first authorized in the EU. The market exclusivity period prevents a successful generic or biosimilar applicant from commercializing its product in the EU until 10 years have elapsed from the initial authorization of the reference product in the EU. The 10-year market exclusivity period can be extended to a maximum of eleven years if, during the first eight years of those 10 years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies.

Pediatric Investigation Plan

In the EEA, marketing authorization applications for new medicinal products not authorized have to include the results of studies conducted in the pediatric population, in compliance with a pediatric investigation plan, or PIP, agreed with the EMA's Pediatric Committee, or PDCO. The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the drug for which marketing authorization is being sought. The PDCO can grant a deferral of the obligation to implement some or all of the measures of the PIP until there are sufficient data to demonstrate the efficacy and safety of the product in adults. Further, the obligation to provide pediatric clinical trial data can be waived by the PDCO when these data is not needed or appropriate because the product is likely to be ineffective or unsafe in children, the disease or condition for which the product is intended occurs only in adult populations, or when the product does not represent a significant therapeutic benefit over existing treatments for pediatric patients. Once the marketing authorization is obtained in all Member States of the EU and study results are included in the product information, even when negative, the product is eligible for six months' supplementary protection certificate extension.

Clinical Trials

Clinical trials of medicinal products in the European Union must be conducted in accordance with European Union and national regulations and the International Conference on Harmonization, or ICH, guidelines on GCPs. Additional GCP guidelines from the European Commission, focusing in particular on traceability, apply to clinical trials of advanced therapy medicinal products. If the sponsor of the clinical trial is not established within the European Union, it must appoint an entity within the European Union to act as its legal representative. The sponsor must take out a clinical trial insurance policy, and in most EU countries, the sponsor is liable to provide 'no fault' compensation to any study subject injured in the clinical trial.

Prior to commencing a clinical trial, the sponsor must obtain a clinical trial authorization from the competent authority, and a positive opinion from an independent ethics committee. The application for a clinical trial authorization must include, among other things, a copy of the trial protocol and an investigational medicinal product dossier containing information about the manufacture and quality of the medicinal product under investigation. Clinical trials in the European Union are regulated under European Council Directive 2001/20/EC (Clinical Trials Directive) on the implementation of GCP in the conduct of clinical trials of medicinal products for human use. In April 2014, Regulation EU No 536/2014 (Clinical Trials Regulation) was adopted to replace the Clinical Trials Directive. The Clinical Trials Regulation is intended to simplify the rules for clinical trial authorization and standards of performance. The implementation of the Clinical Trials Regulation depends on confirmation of full functionality of the Clinical Trials Information System (CTIS) through an independent audit, which commenced in September 2020. The system is currently planned to go live in December 2021. The new clinical trial portal and database will be maintained by the EMA in collaboration with the European Commission and the European Union Member States. The Clinical Trials Directive requires the sponsor of an investigational medicinal product to obtain a clinical trial authorization, or CTA, much like an IND in the U.S., from the national competent authority of a European Union Member State in which the clinical trial is to be conducted. The CTA application must be accompanied by an investigational medicinal product dossier with supporting information

prescribed by the Council Directive and corresponding national laws of the Member States and further detailed in applicable guidance, including the European Commission Communication 2010/C 82/01. A clinical trial may only be commenced after an Ethics Committee has given its approval. Any substantial changes to the trial protocol or other information submitted with the clinical trial applications must be notified to or approved by the relevant competent authorities and ethics committees. Medicines used in clinical trials must be manufactured in accordance with cGMP. Other national and European Union-wide regulatory requirements also apply.

Privacy and Data Protection Laws

We are also subject to laws and regulations in non-U.S. countries covering data privacy and the protection of health-related and other personal information. EU member states and other jurisdictions have adopted data protection laws and regulations, which impose significant compliance obligations. Laws and regulations in these jurisdictions apply broadly to the collection, use, storage, disclosure, processing and security of personal information that identifies or may be used to identify an individual, such as names, contact information, and sensitive personal data such as health data. These laws and regulations are subject to frequent revisions and differing interpretations, and have generally become more stringent over time.

As of May 25, 2018, Regulation 2016/676, known as the General Data Protection Regulation, or GDPR, replaced the Data Protection Directive with respect to the Processing of personal data in the European Union. The GDPR imposes many requirements for controllers and processors of personal data, including, for example, higher standards for obtaining consent from individuals to process their personal data, more robust disclosures to individuals and a strengthened individual data rights regime, shortened timelines for data breach notifications, limitations on retention and secondary use of information, increased requirements pertaining to health data and pseudonymized (i.e., key-coded) data and additional obligations when we contract third-party processors in connection with the processing of the personal data. The GDPR allows EU member states to make additional laws and regulations further limiting the Processing of genetic, biometric or health data. Failure to comply with the requirements of GDPR and the applicable national data protection laws of the EU member states could subject us to regulatory sanctions, delays in clinical trials, criminal prosecution and/or civil fines or penalties. Changes to the GDPR and applicable national data privacy laws, including with respect to how these laws should be applied in the context of clinical trials or other transactions from which we may gain access to personal data, could increase our compliance costs and exposure to potential liability.

Employees and Human Capital Resources

As of, 2021, we had full-time employees and part-time employees, of whom have a Ph.D. or M.D. and of whom were engaged in research and development activities. None of our employees are represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

Our human capital resource objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and additional employees. The principal purposes of our equity incentive plans are to attract, retain and motivate selected employees, consultants and directors through the granting of stock-based compensation awards.

Executive Officers and Directors

The following table sets forth the names, ages and positions of our executive officers and directors as of June 1, 2020:

NAME	AGE	POSITION(S)
Executive Officers and Employee Directors:		
Raju S. Mohan, Ph.D.	64	Chief Executive Officer and Director
Martin D. Auster, M.D.	46	Chief Financial Officer
Christopher W. Krueger, J.D., M.B.A.	53	Chief Business Officer
John M. Nuss, Ph.D.	62	Chief Scientific Officer
Non-Employee Directors:		
Sheila Gujrathi, M.D.	50	Chair of the Board
Jigar R. Choksey, M.B.A. (1)	35	Director
Richard S. Gaster, M.D., Ph.D. (2) (3)	37	Director
Aaron E. Royston, M.D., M.B.A. (1)	36	Director
Somasundaram Subramaniam, M.B.A. (2) (3)	66	Director
William White, J.D., M.P.P (1)	48	Director

(1) Member of the audit committee.

(2) Member of the compensation committee.

(3) Member of the corporate governance and nominating committee.

Executive Officers and Employee Directors

Raju S. Mohan, Ph.D. Dr. Mohan founded the Company and has served as our Chief Executive Officer and as a member of our board of directors since the Company's inception in November 2018. Dr. Mohan previously founded Akarna Therapeutics in October 2014 and served as its chief executive officer from its founding until it was acquired by Allergan in September 2016. In addition, Dr. Mohan founded Oppilan Pharma Ltd. in May 2015 (acquired by us in February 2021), Zomagen Biosciences Ltd. in July 2018 (acquired by us in February 2021) and Vimalan Biosciences in October 2017, all immunology-focused specialty pharmaceutical companies. From 2006 to 2011, Dr. Mohan served as Vice President and head of the San Diego site for Exelixis, Inc. From 2004 to 2006, Dr. Mohan served as Vice President of Chemistry at X-Ceptor Therapeutics (acquired by Exelixis). Dr. Mohan started his pharmaceutical career at Berlex Biosciences in 1987, a subsidiary of Bayer/Schering AG. Dr. Mohan received a Ph.D. in Chemistry from the University of Illinois, Urbana-Champaign and a master's degree from the Indian Institute of Technology.

Martin D. Auster, M.D. Dr. Auster has served as our Chief Financial Officer since May 2021. Dr. Auster previously served as managing director, biotechnology analyst at Credit Suisse since October 2017. While at Credit Suisse, Dr. Auster was head of the global biotech research team, with a coverage focus on small/mid cap biotechnology companies. From October 2016 to October 2017, Dr. Auster was a senior biotechnology analyst at UBS Securities. Prior to that, Dr. Auster held executive positions at Ascendis Pharma A/S as Chief Business Officer from May 2014 to September 2016 and at United Therapeutics as Vice President, Business Development and Strategic Finance from March 2009 to May 2014. Earlier in his career, Dr. Auster also held positions in the investment banking industry, including as a senior biotechnology analyst at Wachovia Securities from March 2003 to February 2006 and a senior analyst/healthcare-focused portfolio manager at GLG Partners, Inc. from February 2006 to March 2009. Dr. Auster holds a B.A. from the University of Michigan and an M.D. from the University of Texas Medical Branch at Galveston.

Christopher W. Krueger, J.D., M.B.A. Mr. Krueger has served as our Chief Business Officer since our inception in November 2018. Mr. Krueger has also served as chief executive officer of Oppilan Pharma Limited (acquired by us in February 2021) since December 2015 and chief business officer of Zomagen Biosciences Ltd. (acquired by us in February 2021) since 2018. Mr. Krueger served as chief business officer at Akarna Therapeutics Ltd. (acquired by Allergan Plc) from 2014 to 2016, as a senior business advisor to multiple biotech companies from 2010 to 2016, as chief business officer at Ardea Biosciences, Inc. (acquired by AstraZeneca Plc) from 2007 to 2010, senior vice president at Xencor, Inc. from 2004 to 2006, chief business officer at X-Ceptor Therapeutics Inc. (acquired by Exelixis, Inc.) from 2002 to 2004, and general counsel and

vice president of strategic alliances at Aurora Biosciences Corporation (acquired by Vertex Pharmaceuticals Inc.) from 2000 to 2002. Earlier in Mr. Krueger's career, he was an attorney at Cooley LLP. Chris holds a J.D. and M.B.A. in Finance from the University of Southern California and a B.A. in Economics from the University of California, San Diego.

John M. Nuss, Ph.D. Dr. Nuss has served as our Chief Scientific Officer since January 2019. Prior to joining Ventyx, Dr. Nuss was Vice President of Drug Discovery at the Ferring Research Institute from April 2012 to January 2017, where he was responsible for global drug discovery activities. From April 2000 to April 2011, Dr. Nuss served as Senior Vice President of Chemistry at Exelixis Inc. Earlier in his career, he held positions of increasing responsibility in discovery at Chiron Corporation and served as an assistant professor of chemistry at the University of California, Riverside. Dr. Nuss received a bachelor's degree in chemistry from the University of Kansas, a Ph.D. in organic chemistry of the University of Wisconsin, Madison, and completed a NIH postdoctoral fellowship in organic synthesis at Stanford University.

Each of our executive officers serves at the discretion of our board of directors and holds office until his successor is duly elected and qualified or until his or her earlier resignation or removal.

Non-Employee Directors

Sheila Gujrathi, M.D. Dr. Gujrathi has served as member of our board of directors since May 2021. Dr. Gujrathi currently serves on the board of directors of Turning Point Therapeutics, Inc, Five Prime Therapeutics, Inc., Ambryx Inc. and Janux Therapeutics Inc. Dr. Gujrathi previously co-founded Gossamer Bio, Inc. in January 2018 and served as President and Chief Executive Officer from July 2018 to November 2020. Prior to founding Gossamer Bio, Dr. Gujrathi served as Chief Medical Officer of Receptos, Inc. from June 2011 until the company's acquisition by Celgene Corporation in August 2015. Prior to joining Receptos, she was Vice President of the Global Clinical Research Group in Immunology at Bristol-Myers Squibb from 2008 to 2011. Dr. Gujrathi also worked at Genentech, Inc. from 2002 to 2008 where she held roles of increasing responsibility in the Immunology, Tissue Growth and Repair clinical development group, and served as the Avastin Franchise Team Leader. From 1999 to 2002, Dr. Gujrathi was a management consultant at McKinsey & Company in the healthcare practice where she provided strategic advice on a variety of projects in the healthcare and pharmaceutical industry. Dr. Gujrathi received her B.S. with highest distinction in Biomedical Engineering and her M.D. from Northwestern University in their accelerated Honors Program in Medical Education. She completed her Internal Medicine Internship and Residency at Brigham and Women's Hospital, Harvard Medical School. She received additional training at University of California, San Francisco and Stanford University in their Allergy and Immunology Fellowship Program.

We believe Dr. Gujrathi's is qualified to serve on our board of directors because of her extensive service as director and officer of multiple biotechnology companies.

Jigar R. Choksey, M.B.A. Mr. Choksey has served on our board of directors since March 2021. He has served as a principal at Third Point LLC since October 2020. At Third Point, Mr. Choksey leads investments in public and private healthcare companies. Previously, he was the healthcare sector lead and assistant portfolio manager at Highline Capital from June 2017 to October 2020. Prior to Highline, he worked at Magnetar Capital from October 2014 to May 2017 covering healthcare and as an investment banker in the mergers and acquisitions and restructuring group at Evercore Partners from August 2012 to October 2014. Mr. Choksey began his career as a management consultant at Booz & Company in October 2007. He graduated magna cum laude from Northwestern University with a B.S. in Biomedical Engineering and Economics and earned an M.B.A. from the Wharton School at the University of Pennsylvania.

We believe Mr. Choksey is qualified to serve on our board of directors because of his extensive experience investing in the healthcare sector.

Richard S. Gaster, M.D., Ph.D. Dr. Gaster has served on our board of directors since March 2021. Dr. Gaster is a partner at venBio Partners and has been with venBio Partners since April 2017. Dr. Gaster has served on the board of directors of Elevation Oncology, Inc. since November 2020, Attralus, Inc. since August 2020, Stargazer Pharmaceuticals, Inc. since April 2020, NorthSea Therapeutics B.V. since January 2020, Aeovian Pharmaceuticals Inc. since October 2019, and Arrakis Therapeutics, Inc. since April 2019. Dr. Gaster also served on the board of directors of Pharvaris N.V. from August 2019 to May 2021. Prior to joining venBio Partners, Dr. Gaster served as the head of translational medicine at Pliant Therapeutics, Inc. from February 2016 to April 2017. Dr. Gaster began his career as a resident physician in Harvard's Plastic and

Reconstructive Surgery Program in 2013. Dr. Gaster holds a BSE in Bioengineering from the University of Pennsylvania where he graduated summa cum laude. Dr. Gaster received his M.D. and Ph.D. in Bioengineering from Stanford University in the Medical Scientist Training Program.

We believe Dr. Gaster is qualified to serve on our board of directors because of his clinical and biotechnology industry experience and his service on the boards of directors of other biopharmaceutical companies.

Aaron E. Royston, M.D., M.B.A. Dr. Royston has served as a member of our board of directors since March 2021. Dr. Royston is a managing partner at venBio Partners and has been with venBio Partners since 2015. Prior to joining venBio Partners, Dr. Royston worked for Vivo Capital, a global life sciences investment firm from July 2014 to November 2015, Previously, Dr. Royston worked at Bain & Company, Inc. from July 2013 to July 2014 where he advised biotechnology companies on a broad range of strategic and operational issues. Earlier in his career, Dr. Royston coordinated clinical research at Mount Sinai Medical Center, where his research has been published and presented in multiple medical journals and conferences. In 2011, Dr. Royston was recognized by the Obama Administration as a Champion of Change for his work in technology and innovation. Dr. Royston previously served on the boards of directors of Akero Therapeutics, a biotechnology company, from June 2018 to August 2019 and Menlo Therapeutics Inc., a biotechnology company, from June 2017 to August 2019. Dr. Royston currently serves on the board of directors of several private companies. Dr. Royston received a B.S. in biological sciences from Duke University, and an M.D. and M.B.A. from the University of Pennsylvania.

We believe that Dr. Royston is qualified to serve on our board of directors because of his clinical and biotechnology industry experience and his service on the boards of directors of other biopharmaceutical companies.

Somasundaram Subramaniam, M.B.A. Mr. Subramaniam has served as a member of our board of directors since its founding. Mr. Subramaniam is a co-founder and managing partner of New Science Ventures, a venture capital firm. From 2010 to 2018, Mr. Subramaniam served on the board of directors of iCAD, a publicly-held medical device company. He also serves on the board of several of NSV's portfolio companies, including Cambridge Epigenetix, Inc. since October 2014, Resolve Therapeutics, Inc. since May 2011, and NorthSea Therapeutics, Inc. since December 2017. Prior to co-founding New Science Ventures in 2004, Mr. Subramaniam was a director at McKinsey & Co., a global consulting firm. Mr. Subramaniam received a B. Tech from the Indian Institute of Technology in India and an M.B.A. from Harvard Business School.

We believe Mr. Subramaniam is qualified to serve on our board of directors because of his prior board experience and extensive experience investing in the healthcare sector.

William White, J.D., M.P.P. Mr. White has served as a member of our board of directors since May 2021. Since April 2019, Mr. White has served as chief financial officer and head of corporate development and treasurer of Akero Therapeutics. From September 2017 to March 2019, Mr. White served as a managing director and head of US life sciences investment banking at Deutsche Bank. From May 2006 to September 2017, Mr. White was a managing director in healthcare investment banking at Citigroup. From November 2000 to March 2006, Mr. White served as an associate and vice president in healthcare investment banking at Goldman, Sachs & Co. Mr. White currently serves on the board of directors of Disc Medicine, Inc., a private hematology company. Mr. White received an A.B. from Princeton University, an M.P.P. from Harvard University and a J.D. from Columbia University.

We believe Mr. White is qualified to serve on our board of directors because of his extensive financial leadership in the life sciences industry and in health care investment banking.

Family Relationships

There are no family relationships among any of our directors or executive officers.

Board Composition and Election of Directors

Director Independence

Upon the completion of this offering, we anticipate that our common stock will be listed on the Nasdaq Global Market. Under the rules of Nasdaq, independent directors must comprise a majority of a listed company's board of directors within one year of the completion of this offering. In addition, the rules of Nasdaq require that,

subject to specified exceptions, each member of a listed company's audit, compensation and corporate governance and nominating committees be independent. Audit committee members and compensation committee members must also satisfy the independence criteria set forth in Rule 10A-3 and Rule 10C-1, respectively, under the Exchange Act. Under the rules of Nasdaq, a director will only qualify as an "independent director" if, in the opinion of that company's board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

To be considered to be independent for purposes of Rule 10A-3 and under the rules of Nasdaq, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors or any other board committee: (1) accept, directly or indirectly, any consulting, advisory or other compensatory fee from the listed company or any of its subsidiaries or (2) be an affiliated person of the listed company or any of its subsidiaries.

To be considered independent for purposes of Rule 10C-1 and under the rules of Nasdaq, the board of directors must affirmatively determine that each member of the compensation committee is independent, including a consideration of all factors specifically relevant to determining whether the director has a relationship to the company which is material to that director's ability to be independent from management in connection with the duties of a compensation committee member, including, but not limited to: (i) the source of compensation of such director, including any consulting, advisory or other compensatory fee paid by the company to such director and (ii) whether such director is affiliated with the company, a subsidiary of the company or an affiliate of a subsidiary of the company.

Our board of directors undertook a review of its composition, the composition of its committees and the independence of our directors and considered whether any director has a material relationship with us that could compromise his or her ability to exercise independent judgment in carrying out his or her responsibilities. Based upon information requested from and provided by each director concerning his background, employment and affiliations, including family relationships, our board of directors has determined that all of our directors, other than Raju Mohan, Ph.D., our chief executive officer, do not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is "independent" as that term is defined under the rules of Nasdaq.

In making these determinations, our board of directors considered the current and prior relationships that each non-employee director has with our company and all other facts and circumstances our board of directors deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each non-employee director, and the transactions involving them described in the section titled "Certain Relationships and Related Party Transactions."

Classified Board of Directors

Our board of directors currently consists of six members. After the completion of this offering, the number of directors will be fixed by our board of directors, subject to the terms of our amended and restated certificate of incorporation and amended and restated bylaws. Each of our current directors will continue to serve as a director until the election and qualification of his or her successor, or until his or her earlier death, resignation or removal.

In accordance with the terms of our amended and restated certificate of incorporation that will go into effect immediately prior to the completion of this offering, our board of directors will be divided into three classes with staggered, three-year terms. At each annual meeting of stockholders, the directors whose terms then expire will be eligible for reelection until the third annual meeting following reelection. Effective upon the completion of this offering, our directors will be divided among the three classes as follows:

- the Class I directors will be , and their terms will expire at our first annual meeting of stockholders following this offering;
- the Class II directors will be , and their terms will expire at our second annual meeting of stockholders following this offering; and
- the Class III directors will be , and their terms will expire at our third annual meeting of stockholders following this offering.

At each annual meeting of stockholders, upon the expiration of the term of a class of directors, the successor to each such director in the class will be elected to serve from the time of election and qualification until the third annual meeting following his or her election and until his or her successor is duly elected and qualified, in

accordance with our amended and restated certificate of incorporation. Any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one third of our directors.

This classification of our board of directors may have the effect of delaying or preventing changes in control of our company.

Board Leadership Structure

Our board of directors is currently chaired by Sheila Gujrathi, M.D. As a general policy, our board of directors believes that separation of the positions of chair of our board of directors and chief executive officer reinforces the independence of our board of directors from management, creates an environment that encourages objective oversight of management's performance and enhances the effectiveness of our board of directors as a whole. As such, Raju Mohan, Ph.D. serves as our chief executive officer while Dr. Gujrathi serves as the chair of our board of directors but is not an officer. We currently expect and intend the positions of chair of our board of directors and chief executive officer to continue to be held by two individuals in the future.

Role of the Board in Risk Oversight

Our board of directors has an active role, as a whole and also at the committee level, in overseeing the management of our risks. Our board of directors is responsible for general oversight of risks and regular review of information regarding our risks, including credit risks, liquidity risks and operational risks. The compensation committee is responsible for overseeing the management of risks relating to our executive compensation plans and arrangements. The audit committee is responsible for overseeing the management of risks relating to accounting matters and financial reporting. Although each committee is responsible for evaluating certain risks and overseeing the management of such risks, our entire board of directors is regularly informed through discussions from committee members about such risks. Our board of directors believes its administration of its risk oversight function has not negatively affected the board of directors' leadership structure.

Committees of the Board of Directors

Our board of directors has established three standing committees—audit, compensation and nominating and corporate governance—each of which operates under a charter that has been approved by our board of directors and has the composition and the responsibilities described below.

Audit Committee

Upon the effectiveness of the registration statement of which this prospectus forms a part, the members of our audit committee will be Mr. Choksey, Dr. Royston, and Mr. White. Mr. White will be the chair of our audit committee and will be our audit committee financial expert, as that term is defined under the SEC rules implementing Section 407 of the Sarbanes-Oxley Act, and possesses financial sophistication, as defined under the rules of Nasdaq. Our audit committee will oversee our corporate accounting and financial reporting process and assist our board of directors in monitoring our financial systems. Our audit committee will also:

- select and hire the independent registered public accounting firm to audit our financial statements;
- help to ensure the independence and performance of the independent registered public accounting firm;
- approve audit and non-audit services and fees;
- review financial statements and discuss with management and the independent registered public accounting firm our annual audited and quarterly financial statements, the results of the independent audit and the quarterly reviews and the reports and certifications regarding internal controls over financial reporting and disclosure controls;
- prepare the audit committee report that the SEC requires to be included in our annual proxy statement;
- review reports and communications from the independent registered public accounting firm;
- review the adequacy and effectiveness of our internal controls and disclosure controls and procedure;
- review our policies on risk assessment and risk management;
- review and monitor conflicts of interest situations, and approve or prohibit any involvement in matters that may involve a conflict of interest or taking of a corporate opportunity;

- review related party transactions; and
- establish and oversee procedures for the receipt, retention and treatment of accounting related complaints and the confidential submission by our employees of concerns regarding questionable accounting or auditing matters.

Our audit committee will operate under a written charter, to be effective prior to the completion of this offering, which will satisfy the applicable rules of the SEC and the listing standards of Nasdaq.

Compensation Committee

Upon the effectiveness of the registration statement of which this prospectus forms a part, the members of our compensation committee will be . will be the chair of our compensation committee. Our compensation committee will oversee our compensation policies, plans and benefits programs. The compensation committee will also:

- oversee our overall compensation philosophy and compensation policies, plans and benefit programs;
- review and approve or recommend to the board of directors for approval compensation for our executive officers and directors;
- prepare the compensation committee report that the SEC requires to be included in our annual proxy statement; and
- administer our equity compensation plans.

Our compensation committee will operate under a written charter, to be effective prior to the completion of this offering, which will satisfy the applicable rules of the SEC and the listing standards of Nasdaq.

Nominating and Corporate Governance Committee

Upon the effectiveness of the registration statement of which this prospectus forms a part, the members of our corporate governance and nominating committee will be . will be the chair of our corporate governance and nominating committee. Our corporate governance and nominating committee will oversee and assist our board of directors in reviewing and recommending nominees for election as directors. Specifically, the corporate governance and nominating committee will:

- identify, evaluate and make recommendations to our board of directors regarding nominees for election to our board of directors and its committees;
- consider and make recommendations to our board of directors regarding the composition of our board of directors and its committees;
- review developments in corporate governance practices;
- evaluate the adequacy of our corporate governance practices and reporting; and
- evaluate the performance of our board of directors and of individual directors.

Our corporate governance and nominating committee will operate under a written charter, to be effective prior to the completion of this offering, which will satisfy the applicable rules of the SEC and the listing standards of Nasdaq.

Compensation Committee Interlocks and Inside Participation

None of our executive officers currently serves, or in the past fiscal year has served, as a member of the board of directors or compensation committee (or other board committee performing equivalent functions or, in the absence of any such committee, the entire board of directors) of any entity that has one or more executive officers serving on our board of directors or compensation committee.

Code of Business Conduct and Ethics

Prior to the completion of this offering, we intend to adopt a written code of business conduct and ethics that will apply to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller or persons performing similar functions. Following this offering, the code of business conduct and ethics will be available on our website at www.ventyxbio.com. We intend to disclose future amendments to such code, or any waivers of its requirements, applicable to any principal executive officer, principal financial officer, principal accounting officer or controller or persons performing similar functions or our directors on our website identified above. Information contained on the website is not incorporated by reference into this prospectus and should not be considered to be part of this prospectus.

Director Compensation

Prior to this offering, we have not implemented a formal policy with respect to compensation payable to our non-employee directors. During the year ended December 31, 2020, no members of our board of directors received any compensation from us in their roles as directors. However, we reimburse our directors for expenses associated with attending meetings of our board of directors and its committees. For more information about the amounts payable to Raju Mohan, Ph.D. in his capacity as our chief executive officer, see the section titled “Executive Compensation.”

Our board of directors intends to adopt a director compensation policy that will become applicable to all our non-employee directors, effective upon the completion of this offering.

EXECUTIVE COMPENSATION

This section discusses the material components of the executive compensation program for our named executive officers, who are named in the "Summary Compensation Table" below.

Raju Mohan, Ph.D., our chief executive officer, Christopher Krueger, J.D., M.B.A., our chief business officer, and John Nuss, Ph.D., our chief scientific officer, were our only executive officers during 2020 and, accordingly, are our named executive officers for 2020. Our other current executive officer, Martin Auster, M.D., our chief financial officer, commenced employment in May 2021.

Summary Compensation Table

The following table sets forth information regarding the compensation of our named executive officers for the year ended December 31, 2020. We have included certain information in parts of the following narrative regarding the compensation of Dr. Auster where it may be material to an understanding of our executive compensation program.

NAME AND PRINCIPAL POSITION	YEAR	SALARY ($)[1][2]	BONUS ($)[3][4]	OPTION AWARDS ($)[5][6][7]	ALL OTHER COMPENSATION ($)[8][9][10]	TOTAL ($)
Raju Mohan, Ph.D.	2020	36,565	20,085	10,906	3,574	71,130
Chief Executive Officer						
Christopher Krueger, J.D., M.B.A.	2020	33,887	9,502	10,906	1,288	55,583
Chief Business Officer						
John Nuss, Ph.D.	2020	97,242	27,476	10,906	8,812	144,436
Chief Scientific Officer						

(1) These amounts reflect amounts paid to Kalika pursuant to the Kalika Services Agreement and in consideration for the services provided by each of Dr. Mohan, Mr. Krueger and Dr. Nuss. For more information, see the section titled "Certain Relationships and Related Party Transactions."

(2) In connection with services provided to Zomagen and Oppilan, our subsidiaries as of February 2021, for the year ended December 31, 2020, (i) Dr. Mohan earned an aggregate salary of $217,911, (ii) Mr. Krueger earned an aggregate salary of $218,895, and (iii) Dr. Nuss earned an aggregate salary of $179,384. These amounts reflect amounts paid to Kalika pursuant to the Kalika Services Agreement and in consideration for the services provided by each of Dr. Mohan, Mr. Krueger and Dr. Nuss. For more information, see the section titled "Certain Relationships and Related Party Transactions."

(3) These amounts reflect amounts paid to Kalika in 2021 pursuant to the Kalika Services Agreement and in consideration for the services provided by each of Dr. Mohan, Mr. Krueger and Dr. Nuss in 2020. For more information, see the section titled "Certain Relationships and Related Party Transactions."

(4) In connection with services provided to Zomagen and Oppilan, our subsidiaries as of February 2021, for the year ended December 31, 2020, (i) Dr. Mohan earned an aggregate discretionary bonus of $120,511, (ii) Mr. Krueger earned an aggregate discretionary bonus of $61,761, and (iii) Dr. Nuss earned an aggregate discretionary bonus of $50,374. These amounts reflect amounts paid to Kalika in 2021 pursuant to the Kalika Services Agreement and in consideration for the services provided by each of Dr. Mohan, Mr. Krueger and Dr. Nuss in 2020. For more information, see the section titled "Certain Relationships and Related Party Transactions."

(5) The amounts disclosed represent the aggregate grant date fair value of the stock options granted to our named executive officers during fiscal year 2020 under our 2019 Equity Incentive Plan, as computed in accordance with Financial Accounting Standard Board Accounting Standards Codification Topic 718 for stock-based compensation transactions (ASC 718). As required by SEC rules, the amounts shown exclude the impact of estimated forfeitures related to service-based vesting conditions. The assumptions used in calculating the grant date fair value of the stock options are set forth in Note 10 to our financial statements included elsewhere in this prospectus. This amount does not reflect the actual economic value that may be realized by the named executive officer.

(6) In connection with services provided to Oppilan, our subsidiary as of February 2021, for the year ended December 31, 2020, (i) Dr. Mohan received option awards with a fair value of $18,802, (ii) Mr. Krueger received option awards with a fair value of $18,802, and (iii) Dr. Nuss received option awards with a fair value of $18,802.

(7) In connection with services provided to Zomagen, our subsidiary as of February 2021, for the year ended December 31, 2020, (i) Dr. Mohan received stock awards with a fair value of $63,544, (ii) Mr. Krueger received stock awards with a fair value of $4,346, and (iii) Dr. Nuss received stock awards with a fair value of $63,544.

(8) Other Compensation for each of the named executive officers consists of the employer paid portion of medical, dental & vision insurance.

(9) These amounts disclosed represent the amount paid to Kalika pursuant to the Kalika Services Agreement and in consideration for the service's provided by each of Dr. Mohan, Mr. Krueger and Dr. Nuss. For more information, see the section titled "Certain Relationships and Related Party Transactions."

(10) In connection with services provided to Zomagen and Oppilan, our subsidiaries as of February 2021, for the year ended December 31, 2020, (i) Dr. Mohan received an aggregate of $21,298, (ii) Mr. Krueger received an aggregate of $8,317, and (iii) Dr. Nuss received an aggregate of $16,255, in each case, in Other Compensation consisting of the employer paid portion of medical, dental & vision insurance. These amounts reflect amounts paid to Kalika pursuant to the Kalika Services Agreement and in consideration for the services provided by each of Dr. Mohan, Mr. Krueger and Dr. Nuss. For more information, see the section titled "Certain Relationships and Related Party Transactions."

Outstanding Equity Awards at Fiscal Year-End

The following table shows grants of stock options to each of our named executive officers outstanding at December 31, 2020, all of which were granted under our 2019 Equity Incentive Plan, as amended:

		OPTION AWARDS			
NAME	GRANT DATE	NUMBER OF SECURITIES UNDERLYING UNEXERCISED OPTIONS (#) EXERCISABLE(1)	NUMBER OF SECURITIES UNDERLYING UNEXERCISED OPTIONS UNEXERCISABLE(1)	OPTION EXERCISE PRICE ($)(2)(1)	OPTION EXPIRATION DATE
Raju Mohan, Ph.D.	05/01/2020	179,982	745,642	$0.0176456	05/01/2030
Chief Executive Officer					
Christopher Krueger, J.D., M.B.A.	03/27/2019	565,664	359,968	$0.0100832	03/27/2029
Chief Business Officer	05/01/2020	179,982	745,642	$0.0176456	05/01/2030
John Nuss, Ph.D.	03/27/2019	1,131,324	719,933	$0.0100832	03/27/2029
Chief Scientific Officer	05/01/2020	179,982	745,642	$0.0176456	05/01/2030

(1) Each of the outstanding options to purchase shares of our common stock was granted pursuant to our 2019 Equity Incentive Plan, as amended. On February 25, 2021, the company effected a forward stock split, such that each share of our common stock was split, subdivided and changed into 7.933972 shares of common stock. Accordingly, the share totals and exercise prices shown in the table above reflect the post-stock split values.

(2) This column represents the fair market value of a share of our common stock on the date of grant, as determined by our board of directors.

Employment Arrangements with Our Named Executive Officers

Below are descriptions of our employment agreements or offer letters with our named executive officers, including a discussion of the severance pay and other benefits to be provided in connection with a termination of employment and/or a change in control under the arrangements with our named executive officers. Each of our named executive officers and Dr. Auster is employed "at will."

Raju Mohan, Ph.D.

We entered into an employment agreement with Raju Mohan, Ph.D. on May 11, 2021, setting forth the terms of his employment as our chief executive officer. Pursuant to his employment agreement, Dr. Mohan is entitled to an annual base salary of $420,000, and is eligible to receive an annual bonus with a target amount equal to 50% of his then-current annual base salary.

Pursuant to Dr. Mohan's employment agreement, if we terminate Dr. Mohan's employment other than for cause (as defined below) or Dr. Mohan terminates his employment for good reason (as defined below), and other than as a result of death or disability, in either case prior to a change in control (as defined below) or more than 12 months following a change in control, he is entitled to the following payments and benefits, subject to the timely execution and non-revocation of a general release of claims in our favor: (1) continued payment of his base salary at the then-current rate for 12 months, paid in accordance to our payroll practices; and (2) payment of the full premium for continued health plan coverage for up to 12 months following the date of termination or, if earlier, up to the date he and his eligible dependents are no longer eligible for continued health plan coverage.

If Dr. Mohan's employment is terminated by us other than for cause or by Dr. Mohan for good reason, in each case within 12 months after a change in control, in lieu of the severance benefits described above, he is entitled to the following payments and benefits, subject to the timely execution and non-revocation of a general release of claims in our favor: (1) continued payment of his base salary at the then-current rate for 12 months, paid in accordance to our payroll practices; (2) payment of the full premium for continued health plan coverage for up to 12 months following the date of termination or, if earlier, up to the date he and his eligible dependents are no longer eligible for continued health plan coverage; and (3) automatic full vesting and exercisability of all of the executive's unvested stock awards.

In the event we terminate Dr. Mohan's employment for cause, or Dr. Mohan terminates his employment without good reason, Dr. Mohan shall be entitled to receive his fully earned but unpaid base salary and any accrued unused vacation time through the effective date of termination. If Dr. Mohan's employment is terminated as a result of his death or disability, he is entitled to receive his fully earned but unpaid base salary and accrued and unused vacation time through the date of termination at the rate then in effect, plus any bonus earned but not yet paid, as of the effective date of his termination.

Dr. Mohan's employment agreement also contains a Section 280G better-off cutback provision, which provides that, in the event that the payments or benefits provided to the executive pursuant to the employment letter or otherwise constitute parachute payments with the meaning of Section 280G of the Code, the payments or benefits to the executive will either be delivered in full or reduced to the extent necessary to avoid an excise tax under Section 4999 of the Code, whichever would result in the executive receiving the largest amount of payments or benefits on an after-tax basis.

For purposes of Dr. Mohan's employment agreement, "change in control" has the same meaning given to such term in our 2019 Plan, as described below.

For purposes of Dr. Mohan's employment agreement, "cause" means (i) an act of dishonesty made by him in connection with his responsibilities as an employee that has caused us to suffer material harm; (ii) his conviction of, or plea of nolo contendere to, a felony or any crime involving fraud, embezzlement or any other act of moral turpitude; (iii) his gross misconduct that has caused us to suffer material harm; (iv) his unauthorized use or disclosure of any proprietary information or trade secrets of ours or any other party to whom he owes an obligation of nondisclosure as a result of his relationship with us; (v) his willful breach of any obligations under any written agreement or covenant with us; (vi) his continued failure to perform his employment duties after he has received a written demand of performance from us which specifically sets forth the factual basis for our belief that he has not substantially performed his duties; provided, that cause shall only exist after; (vii) the board of directors delivers written notice to him of the board of director's determination that cause exists; (viii) such notice sets forth in reasonable detail such facts and circumstances; and (ix) he has failed to fully correct any of the events listed in clauses (iii), (v) and (vi) above, if such events are reasonably capable of being fully corrected, within 10 days following delivery to him of the board of director's written notice of its determination that cause exists.

For purposes of Dr. Mohan's employment agreement, "good reason" means his resignation within 30 days following the expiration of any cure period (discussed below) following the occurrence of one or more of the following, without his express written consent: (i) a material reduction of his duties, position or responsibilities, or the removal of him from such position and responsibilities, either of which results in a material diminution of his authority, duties or responsibilities, unless he is provided with a comparable position (i.e., a position of equal or greater organizational level, duties, authority, compensation and status); provided, however, that a reduction in duties, position or responsibilities solely by virtue of us being acquired and made part of a larger entity (as, for example, when our chief executive officer remains as such following a change in control but is not made the chief executive officer of the acquiring corporation) will not constitute "good reason"; (ii) a material reduction in his base salary (except where there is a reduction applicable to the management team generally); (iii) the failure of us to timely pay or provide to him any portion of his compensation or benefits then due to him; or (iv) a material change in the geographic location of his primary work facility or location; provided, that a relocation of less than 50 miles from his then present location will not be considered a material change in geographic location. Dr. Mohan may not resign for good reason without first providing us with written notice of the acts or omissions constituting the grounds for "good reason" within 90 days of the initial existence of the grounds for "good reason" and a reasonable cure period of not less than 30 days following the date we receive such notice during which such condition must not have been cured.

Martin Auster, M.D.

In April 2021, we entered into an offer letter with Martin Auster, M.D., our chief financial officer. Pursuant to his offer letter Dr. Auster is entitled to an annual base salary of $400,000 and is eligible to receive an annual bonus with a target amount equal to 40% of his then-current annual base salary. In addition, the offer letter provides that, subject to approval by our board, Dr. Auster will be granted (i) an option to purchase an aggregate number of 3,645,800 shares of our common stock and (ii) 911,450 shares of restricted common stock.

Christopher Krueger, J.D., M.B.A.

In March 2021, we entered into an offer letter with Christopher Krueger, J.D., M.B.A., our chief business officer. Pursuant to his offer letter, Mr. Krueger is entitled to an annual base salary of $365,000 and is eligible to receive an annual bonus with a target amount equal to 40% of his then-current annual base salary.

John Nuss, Ph.D.

In March 2021, we entered into an offer letter with John Nuss, Ph.D., our chief scientific officer. Pursuant to his offer letter, Dr. Nuss is entitled to an annual base salary of $365,000 and is eligible to receive an annual bonus with a target amount equal to 40% of his then-current annual base salary.

Potential Payments upon Termination or Change of Control

Prior to the effectiveness of the registration statement of which this prospectus forms a part, we expect that our board of directors will review and may adopt change in control and severance arrangements for our named executive officers and certain other of our key employees. The employment agreement with Raju Mohan, Ph.D. provides for accelerated vesting of all outstanding equity awards, as well as certain other benefits upon a qualifying termination in connection with a change of control of our company. For additional discussion of Dr. Mohan's employment agreement and the change of control benefits provided thereunder, see section titled "—Employment Arrangements with Our Named Executive Officers".

Employee Benefit and Stock Plans

2021 Equity Incentive Plan

Prior to the effectiveness of this offering, we expect that our board of directors will adopt, and our stockholders will approve, our 2021 Plan. The 2021 Plan will be effective on the business day immediately prior to the effective date of the registration statement of which this prospectus forms a part. Our 2021 Plan will provide for the grant of incentive stock options, within the meaning of Section 422 of the Code, to our employees and any of our parent and subsidiary corporations' employees, and for the grant of nonstatutory stock options, restricted stock, restricted stock units, stock appreciation rights, performance units, and performance shares to our employees, directors, and consultants and our subsidiary corporations' employees and consultants.

Authorized Shares. A total of shares of our common stock are reserved for issuance pursuant to our 2021 Plan. In addition, the shares reserved for issuance under our 2021 Plan will also include (1) those shares reserved but unissued under our 2014 Plan as of the date of stockholder approval of the 2021 Plan and (2) shares of our common stock subject to awards granted under our 2019 Plan that, after the date of stockholder approval of the 2021 Plan, expire or otherwise terminate without having been exercised in full or are forfeited to or repurchased by us (provided that the maximum number of shares that may be added to the 2021 Plan pursuant to (1) and (2) is shares). The number of shares available for issuance under our 2021 Plan will also include an annual increase on the first day of each fiscal year beginning with our 2020 fiscal year, equal to the least of:

- shares;
- % of the outstanding shares of our common stock as of the last day of the immediately preceding fiscal year; or
- Such other amount as our board of directors may determine.

If an award expires or becomes unexercisable without having been exercised in full, is surrendered pursuant to an exchange program, or, with respect to restricted stock, restricted stock units, performance units or performance shares, is forfeited to or repurchased by us due to failure to vest, the unpurchased shares (or for awards other than stock options or stock appreciation rights, the forfeited or repurchased shares) will become available for future grant or sale under the 2021 Plan (unless the 2021 Plan has terminated). With respect to stock appreciation rights, only the net shares actually issued will cease to be available under the 2021 Plan and all remaining shares under stock appreciation rights will remain available for future grant or sale under the 2021 Plan (unless the 2021 Plan has terminated). Shares that have actually been issued under the 2021 Plan will not be returned to the 2021 Plan except if shares issued pursuant to awards of restricted stock, restricted stock units, performance shares, or performance units are repurchased by or forfeited to us, such shares will become available for future grant under the 2021 Plan. Shares used to pay the exercise price of an award or satisfy the tax withholding obligations related to an award will become available for future grant or sale under the 2021 Plan. To the extent an award is paid out in cash rather than shares, such cash payment will not result in a reduction in the number of shares available for issuance under the 2021 Plan.

Plan Administration. Our board of directors or one or more committees appointed by our board of directors will administer our 2021 Plan. The compensation committee of our board of directors will initially administer our 2021 Plan. In addition, if we determine it is desirable to qualify transactions under our 2021 Plan as exempt under Rule 16b-3 of the Exchange Act, such transactions will be structured to satisfy the requirements for exemption under Rule 16b-3. Subject to the provisions of our 2021 Plan, the administrator has the power to administer our 2021 Plan and make all determinations deemed necessary or advisable for administering the 2021 Plan, including but not limited to, the power to determine the fair market value of our common stock, select the service providers to whom awards may be granted, determine the number of shares covered by each award, approve forms of award agreements for use under the 2021 Plan, determine the terms and conditions of awards (including, but not limited to, the exercise price, the time or times at which awards may be exercised, any vesting acceleration or waiver or forfeiture restrictions and any restriction or limitation regarding any award or the shares relating thereto), construe and interpret the terms of our 2021 Plan and awards granted under it, prescribe, amend and rescind rules relating to our 2021 Plan, including creating sub-plans, modify or amend each award, including but not limited to the discretionary authority to extend the post-termination exercisability period of awards (except no option or stock appreciation right will be extended past its original maximum term), and allow a participant to defer the receipt of payment of cash or the delivery of shares that would otherwise be due to such participant under an award. The administrator also has the authority to allow participants the opportunity to transfer outstanding awards to a financial institution or other person or entity selected by the administrator and to institute an exchange program by which outstanding awards may be surrendered or cancelled in exchange for awards of the same type, which may have a higher or lower exercise price and/or different terms, awards of a different type, and/or cash or by which the exercise price of an outstanding award is increased or reduced. The administrator's decisions, interpretations, and other actions are final and binding on all participants.

Stock Options. Stock options may be granted under our 2021 Plan. The exercise price of options granted under our 2021 Plan must at least be equal to the fair market value of our common stock on the date of grant. The term of an option may not exceed ten years. With respect to any participant who owns more than 10% of the voting power of all classes of our (or any parent or subsidiary of ours) outstanding stock, the term of an incentive stock option granted to such participant must not exceed five years and the exercise price must equal at least 110% of the fair market value on the grant date. The administrator will determine the methods of payment of the exercise price of an option, which may include cash, shares or other property acceptable to the administrator, as well as other types of consideration permitted by applicable law. After the termination of service of an employee, director, or consultant, he or she may exercise his or her option for the period of time stated in his or her option agreement. In the absence of a specified time in an award agreement, if termination is due to death or disability, the option will remain exercisable for 12 months following the termination of service. In all other cases, in the absence of a specified time in an award agreement, the option will remain exercisable for three months following the termination of service. An option, however, may not be exercised later than the expiration of its term. Subject to the provisions of our 2021 Plan, the administrator determines the other terms of options.

Stock Appreciation Rights. Stock appreciation rights may be granted under our 2021 Plan. Stock appreciation rights allow the recipient to receive the appreciation in the fair market value of our common stock between the exercise date and the date of grant. Stock appreciation rights may not have a term exceeding ten years. After the termination of service of an employee, director or consultant, he or she may exercise his or her stock appreciation right for the period of time stated in his or her stock appreciation rights agreement. In the absence of a specified time in an award agreement, if termination is due to death or disability, the stock appreciation rights will remain exercisable for 12 months following the termination of service. In all other cases, in the absence of a specified time in an award agreement, the stock appreciation rights will remain exercisable for three months following the termination of service. However, in no event may a stock appreciation right be exercised later than the expiration of its term. Subject to the provisions of our 2021 Plan, the administrator determines the other terms of stock appreciation rights, including when such rights become exercisable and whether to pay any increased appreciation in cash or with shares of our common stock, or a combination thereof, except that the per share exercise price for the shares to be issued pursuant to the exercise of a stock appreciation right will be no less than 100% of the fair market value per share on the date of grant.

Restricted Stock. Restricted stock may be granted under our 2021 Plan. Restricted stock awards are grants of shares of our common stock that vest in accordance with terms and conditions established by the administrator. The administrator will determine the number of shares of restricted stock granted to any employee, director, or consultant and, subject to the provisions of our 2021 Plan, will determine the terms and

conditions of such awards. The administrator may impose whatever vesting conditions it determines to be appropriate (for example, the administrator may set restrictions based on the achievement of specific performance goals or continued service to us), except the administrator, in its sole discretion, may accelerate the time at which any restrictions will lapse or be removed. Recipients of restricted stock awards generally will have voting and dividend rights with respect to such shares upon grant without regard to vesting, unless the administrator provides otherwise. Shares of restricted stock that do not vest are subject to our right of repurchase or forfeiture.

Restricted Stock Units. Restricted stock units may be granted under our 2021 Plan. Restricted stock units are bookkeeping entries representing an amount equal to the fair market value of one share of our common stock. Subject to the provisions of our 2021 Plan, the administrator determines the terms and conditions of RSUs, including the vesting criteria and the form and timing of payment. The administrator may set vesting criteria based upon the achievement of company-wide, divisional, business unit or individual goals (including, but not limited to, continued employment or service), applicable federal or state securities laws or any other basis determined by the administrator in its discretion. The administrator, in its sole discretion, may pay earned restricted stock units in the form of cash, in shares or in some combination thereof. In addition, the administrator, in its sole discretion, may accelerate the time at which any restrictions will lapse or be removed.

Performance Units and Performance Shares. Performance units and performance shares may be granted under our 2021 Plan. Performance units and performance shares are awards that will result in a payment to a participant only if performance objectives established by the administrator are achieved or the awards otherwise vest. The administrator will establish performance objectives or other vesting criteria in its discretion, which, depending on the extent to which they are met, will determine the number or the value of performance units and performance shares to be paid out to participants. The administrator may set performance objectives based on the achievement of company-wide, divisional, business unit or individual goals (including, but not limited to, continued employment or service), applicable federal or state securities laws or any other basis determined by the administrator in its discretion. After the grant of a performance unit or performance share, the administrator, in its sole discretion, may reduce or waive any performance objectives or other vesting provisions for such performance units or performance shares. Performance units will have an initial value established by the administrator on or prior to the grant date. Performance shares will have an initial value equal to the fair market value of our common stock on the grant date. The administrator, in its sole discretion, may pay out earned performance units or performance shares in cash, shares, or in some combination thereof.

Outside Directors. All outside (non-employee) directors will be eligible to receive all types of awards (except for incentive stock options) under our 2021 Plan. To provide a maximum limit on the cash compensation and equity awards that can be made to our outside directors, our 2021 Plan provides that in any given fiscal year, an outside director will not be granted cash compensation and equity awards with an aggregate value greater than $ (increased to $ in the fiscal year of his or her initial service as an outside director), with the value of each equity award based on its grant date fair value as determined according to GAAP for purposes of this limit. Any cash compensation paid or awards granted to an individual for his or her services as an employee or consultant (other than as an outside director) will not count toward this limit.

Non-Transferability of Awards. Unless the administrator provides otherwise, our 2021 Plan generally does not allow for the transfer of awards and only the recipient of an award may exercise an award during his or her lifetime. If the administrator makes an award transferrable, such award will contain such additional terms and conditions as the administrator deems appropriate.

Certain Adjustments. In the event of certain changes in our capitalization, to prevent diminution or enlargement of the benefits or potential benefits available under our 2021 Plan, the administrator will adjust the number and class of shares that may be delivered under our 2021 Plan and/or the number, class and price of shares covered by each outstanding award and the numerical share limits set forth in our 2021 Plan.

Dissolution or Liquidation. In the event of our proposed liquidation or dissolution, the administrator will notify participants as soon as practicable and, to the extent not exercised, all awards will terminate immediately prior to the consummation of such proposed transaction.

Merger or Change in Control. Our 2021 Plan provides that in the event of a merger or change in control, as defined under our 2021 Plan, each outstanding award will be treated as the administrator determines, without a participant's consent. The administrator is not required to treat all awards, all awards held by a participant or all awards of the same type similarly.

If a successor corporation does not assume or substitute for any outstanding award, then the participant will fully vest in and have the right to exercise all of his or her outstanding options and stock appreciation rights, all restrictions on restricted stock and restricted stock units will lapse, and for awards with performance-based vesting, unless specifically provided for otherwise under the applicable award agreement or other agreement or policy applicable to the participant, all performance goals or other vesting criteria will be deemed achieved at 100% of target levels and all other terms and conditions met. If an option or stock appreciation right is not assumed or substituted in the event of a change in control, the administrator will notify the participant in writing or electronically that such option or stock appreciation right will be exercisable for a period of time determined by the administrator in its sole discretion and the option or stock appreciation right will terminate upon the expiration of such period.

For awards granted to an outside director, in the event of a change in control, the outside director will fully vest in and have the right to exercise all of his or her outstanding options and stock appreciation rights, all restrictions on restricted stock and restricted stock units will lapse and, for awards with performance-based vesting, unless specifically provided for otherwise under the applicable award agreement or other agreement or policy applicable to the participant, all performance goals or other vesting criteria will be deemed achieved at 100% of target levels and all other terms and conditions met.

Clawback. Awards will be subject to any clawback policy of ours, and the administrator also may specify in an award agreement that the participant's rights, payments and/or benefits with respect to an award will be subject to reduction, cancellation, forfeiture and/or recoupment upon the occurrence of certain specified events. Our board of directors may require a participant to forfeit, return or reimburse us all or a portion of the award and/or shares issued under the award, any amounts paid under the award, and any payments or proceeds paid or provided upon disposition of the shares issued under the award in order to comply with such clawback policy or applicable laws.

Amendment; Termination. The administrator has the authority to amend, alter, suspend or terminate our 2021 Plan, provided such action does not materially impair the rights of any participant. Our 2021 Plan will remain in effect until terminated in accordance with its terms.

2019 Equity Incentive Plan, as Amended

Our 2019 Plan was originally adopted by our board of directors and approved by our stockholders in February 2019. Our 2019 Plan was most recently amended in . Our 2019 Plan allows us to provide incentive stock options, within the meaning of Section 422 of the Code, nonstatutory stock options, stock appreciation rights, restricted stock awards and restricted stock units (each, an "award" and the recipient of such award, a "participant") to eligible employees, directors, officers and consultants of ours and any parent or subsidiary of ours. It is expected that as of one business day prior to the effectiveness of the registration statement of which this prospectus forms a part, our 2019 Plan will be terminated, and we will not grant any additional awards under our 2019 Plan thereafter. However, our 2019 Plan will continue to govern the terms and conditions of the outstanding awards previously granted under our 2019 Plan.

As of June 30, 2021, the following awards were outstanding under our 2019 Plan: stock options covering shares of our common stock.

Plan Administration. Our 2019 Plan is administered by our board of directors or one or more committees appointed by our board of directors. Different committees may administer our 2019 Plan with respect to different service providers. The administrator has all authority and discretion necessary or appropriate to administer our 2019 Plan and to control its operation, including the authority to construe and interpret the terms of our 2019 Plan and the awards granted under our 2019 Plan. The administrator's decisions are final and binding on all participants and any other persons holding awards.

The administrator's powers include the power to institute an exchange program under which (i) outstanding awards are surrendered or cancelled in exchange for awards of the same type (which may have higher or lower exercise prices and different terms), awards of a different type or cash, (ii) participants would have the opportunity to transfer any outstanding awards to a financial institution or other person or entity selected by the administrator, or (iii) the exercise price of an outstanding award is increased or reduced. The administrator's powers also include the power to prescribe, amend and rescind rules and regulations relating to our 2019 Plan, to modify or amend each award and to make all other determinations deemed necessary or advisable for administering our 2019 Plan.

Eligibility. Employees, officers, directors and consultants of ours or our parent or subsidiary companies are eligible to receive awards, provided such consultants render bona fide services not in connection with the offer and sale of securities in a capital-raising transaction and do not directly promote or maintain a market for our securities, in each case, within the meaning of Form S-8 promulgated under U.S. securities laws. Only our employees or employees of our parent or subsidiary companies are eligible to receive incentive stock options.

Stock Options. Stock options have been granted under our 2019 Plan. Subject to the provisions of our 2019 Plan, the administrator determines the term of an option, the number of shares subject to an option, and the time period in which an option may be exercised.

The term of an option is stated in the applicable award agreement, but the term of an option may not exceed 10 years from the grant date. The administrator determines the exercise price of options, which generally may not be less than 100% of the fair market value of our common stock on the grant date, unless expressly determined in writing by the administrator on the option's grant date. However, an incentive stock option granted to an individual who directly or by attribution owns more than 10% of the total combined voting power of all of our classes of stock or of any our parent or subsidiary may have a term of no longer than 5 years from the grant date and will have an exercise price of at least 110% of the fair market value of our common stock on the grant date. In addition, to the extent that the aggregate fair market value of the shares with respect to which incentive stock options are exercisable for the first time by an employee during any calendar year (under all our plans and any parent or subsidiary) exceeds $100,000, such options will be treated as nonstatutory stock options.

The administrator determines how a participant may pay the exercise price of an option, and the permissible methods are generally set forth in the applicable award agreement. If a participant's status as a "service provider" (as defined in our 2019 Plan) terminates, that participant may exercise the vested portion of his or her option for the period of time stated in the applicable award agreement. Vested options generally will remain exercisable for thirty (30) days or such longer period of time as set forth in the applicable award agreement if a participant's status as a service provider terminates for a reason other than death or disability. If a participant's status as a service provider terminates due to death or disability, vested options generally will remain exercisable for six (6) months from the date of termination (or such other longer period as set forth in the applicable award agreement). In no event will an option remain exercisable beyond its original term. If a participant does not exercise his or her option within the time specified in the award agreement, the option will terminate. Except as described above, the administrator has the discretion to determine the post-termination exercisability periods for an option.

Stock Appreciation Rights. Prior to the completion of this offering, we may grant stock appreciation rights under our 2019 Plan. Stock appreciation rights allow the recipient to receive the appreciation in the fair market value of our common stock between the grant date and the exercise date. The per share exercise price for the shares to be issued pursuant to the exercise of a stock appreciation right will be no less than 100% of the fair market value per share of our common stock on the grant date. The term of a stock appreciation right may not exceed 10 years. Stock appreciation rights are generally subject to the same post-termination exercise period rules as options. Subject to the provisions of our 2019 Plan, the administrator determines all other terms of stock appreciation rights, including when such rights vest and become exercisable and whether to pay any increased appreciation in cash or with shares of our common stock, or a combination of both.

Restricted Stock. Prior to the completion of this offering, we may grant restricted stock under our 2019 Plan. Restricted stock awards are grants of shares of our common stock that may be subject to various restrictions, including restrictions on transferability and forfeiture provisions. Subject to the terms of our 2019 Plan, the administrator will determine the number of shares of restricted stock granted and other terms and conditions of such awards. The administrator may impose whatever conditions to vesting it determines to be appropriate, and may, in its sole discretion, accelerate the time at which any restrictions will lapse or be removed. Recipients of restricted stock will have voting and dividend rights with respect to such shares upon grant without regard to vesting, unless the administrator provides otherwise. Shares of restricted stock that have not vested are subject to our right of repurchase or forfeiture.

Restricted Stock Units. Prior to the completion of this offering, we may grant restricted stock units under our 2019 Plan. Restricted stock units are bookkeeping entries with each unit representing an amount equal to the fair market value of one share of our common stock. The administrator determines the terms and conditions of restricted stock units, including the number of units granted, the vesting criteria (which may include accomplishing specified performance criteria or continued service to us) and the form and timing of payment.

The administrator in its sole discretion may reduce or waive any vesting criteria. The administrator determines in its sole discretion whether restricted stock units will be settled in cash, shares of our common stock, or a combination of both. Restricted stock units that do not vest will be forfeited by the recipient and will return to us.

Non-Transferability of Awards. Unless determined otherwise by the administrator, awards may not be sold, pledged, assigned, hypothecated or otherwise transferred in any manner other than by will or by the laws of descent and distribution. In addition, during an applicable participant's lifetime, only that participant may exercise their award. If the administrator makes an award transferable, such award may only be transferred (i) by will, (ii) by the laws of descent and distribution or (iii) as permitted by Rule 701 of the Securities Act.

Certain Adjustments. If there is a dividend or other distribution (whether in the form of cash, shares, other securities or other property), recapitalization, stock split, reverse stock split, reorganization, merger, consolidation, split-up, spin-off, combination, repurchase, exchange of shares or our other securities or other change in our corporate structure affecting the shares, the administrator will make proportionate adjustments to the number and type of shares that may be delivered under our 2019 Plan or the number, type and price of shares covered by each outstanding award. The administrator's determination regarding such adjustments will be final, binding and conclusive.

Dissolution or Liquidation. In the event of our proposed dissolution or liquidation, the administrator will notify each participant as soon as practicable prior to the effective date of such proposed transaction. To the extent it has not been previously exercised, an award will terminate immediately prior to the consummation of such proposed action.

Merger and Change of Control. In the event of our merger with or into another corporation or entity or a change in control, each outstanding award will be treated as the administrator determines, including, without limitation, that (i) awards will be assumed, or substantially equivalent awards will be substituted, by the acquiring or succeeding corporation (or an affiliate thereof) with appropriate adjustments as to the number and kind of shares and prices; (ii) upon written notice to a participant, the participant's awards will terminate upon or immediately prior to the consummation of such merger or change in control; (iii) outstanding awards will vest and become exercisable, realizable or payable, or restrictions applicable to an award will lapse, in whole or in part, prior to or upon consummation of such merger or change in control, and, to the extent the administrator determines, terminate upon or immediately prior to the effectiveness of such merger or change in control; (iv) (A) the termination of an award in exchange for an amount of cash or property, if any, equal to the amount that would have been attained upon the exercise of such award or realization of the participant's rights as of the date of the occurrence of the transaction (and, for the avoidance of doubt, if as of the date of the occurrence of the transaction the administrator determines in good faith that no amount would have been attained upon the exercise of such award or realization of the participant's rights, then such award may be terminated by us without payment) or (B) the replacement of such award with other rights or property selected by the administrator in its sole discretion; or (v) any combination of the foregoing. The administrator will not be obligated to treat all awards, all awards a participant holds or all awards of the same type, similarly.

Amendment and Termination. Our board of directors may, at any time, terminate or amend our 2019 Plan in any respect, including, without limitation, amendment of any form of award agreement or instrument to be executed pursuant to our 2019 Plan. To the extent necessary and desirable to comply with applicable laws, we will obtain stockholder approval of any amendment to our 2019 Plan. No amendment or alteration of our 2019 Plan will impair the rights of a participant, unless mutually agreed otherwise between the participant and the administrator in writing. As noted above, it is expected that as of one business day prior to the effectiveness of the registration statement of which this prospectus forms a part, our 2019 Plan will be terminated and we will not grant any additional awards under our 2019 Plan thereafter.

2021 Employee Stock Purchase Plan

Prior to the effectiveness of this offering, we expect that our board of directors will adopt, and our stockholders will approve, our 2021 ESPP. Our 2021 ESPP will be effective on the business day immediately prior to the effective date of the registration statement of which this prospectus forms a part. We believe that allowing our employees to participate in our 2021 ESPP will provide them with a further incentive towards promoting our success and accomplishing our corporate goals.

Authorized Shares. A total of shares of our common stock will be available for sale under our 2021 ESPP. The number of shares of our common stock that will be available for sale under our 2021 ESPP also

includes an annual increase on the first day of each fiscal year beginning with our 2020 fiscal year, equal to the least of:

- shares;
- % of the outstanding shares of our common stock as of the last day of the immediately preceding fiscal year; or
- such other amount as the administrator may determine.

2021 ESPP Administration. We expect that the compensation committee of our board of directors will administer our 2021 ESPP and will have full and exclusive discretionary authority to construe, interpret, and apply the terms of the 2021 ESPP, delegate ministerial duties to any of our employees, designate separate offerings under the 2021 ESPP, designate our subsidiaries and affiliates as participating in the 2021 ESPP, determine eligibility, adjudicate all disputed claims filed under the 2021 ESPP, and establish procedures that it deems necessary for the administration of the 2021 ESPP, including, but not limited to, adopting such procedures and sub-plans as are necessary or appropriate to permit participation in the 2021 ESPP by employees who are foreign nationals or employed outside the United States. The administrator's findings, decisions and determinations are final and binding on all participants to the full extent permitted by law.

Eligibility. Generally, all of our employees will be eligible to participate if they are customarily employed by us, or any participating subsidiary or affiliate, for at least 20 hours per week and more than five months in any calendar year. The administrator, in its discretion, may, prior to an enrollment date, for all options to be granted on such enrollment date in an offering, determine that an employee who (i) has not completed at least two years of service (or a lesser period of time determined by the administrator) since his or her last hire date, (ii) customarily works not more than 20 hours per week (or a lesser period of time determined by the administrator), (iii) customarily works not more than five months per calendar year (or a lesser period of time determined by the administrator), (iv) is a highly compensated employee within the meaning of Section 414(q) of the Code, or (v) is a highly compensated employee within the meaning of Section 414(q) of the Code with compensation above a certain level or is an officer or subject to disclosure requirements under Section 16(a) of the Exchange Act, is or is not eligible to participate in such offering period.

However, an employee may not be granted rights to purchase shares of our common stock under our 2021 ESPP if such employee:

- immediately after the grant would own capital stock and/or hold outstanding options to purchase such stock possessing 5% or more of the total combined voting power or value of all classes of capital stock of ours or of any parent or subsidiary of ours; or
- holds rights to purchase shares of our common stock under all employee stock purchase plans of ours or any parent or subsidiary of ours that accrue at a rate that exceeds $25,000 worth of shares of our common stock for each calendar year in which such rights are outstanding at any time.

Offering Periods. Our 2021 ESPP will include a component that allows us to make offerings intended to qualify under Section 423 of the Code and a component that allows us to make offerings not intended to qualify under Section 423 of the Code to designated companies, as described in our 2021 ESPP. Our 2021 ESPP will provide for consecutive, overlapping -month offering periods. The offering periods will be scheduled to start on the first trading day on or after and of each year, except the first offering period will commence on the first trading day on or after the effective date of the registration statement of which this prospectus forms a part and will end on the first trading day on or before , 2021, and the second offering period will commence on the last trading day on or after , 2021.

Contributions. Our 2021 ESPP will permit participants to purchase shares of our common stock through contributions (in the form of payroll deductions or otherwise to the extent permitted by the administrator) of up to % of their eligible compensation, which includes a participant's base straight time gross earnings but excludes payments for incentive compensation, bonuses, payments for overtime and shift premium, equity compensation income and other similar compensation. Unless otherwise determined by the administrator, a participant may make a onetime decrease (but not increase) to the rate of his or her contributions to 0% during an offering period.

Exercise of Purchase Right. Amounts contributed and accumulated by the participant will be used to purchase shares of our common stock at the end of each offering. A participant may purchase a maximum of shares of our common stock during an offering period. The purchase price of the shares will be 85% of the

lower of the fair market value of our common stock on the first trading day of the offering period or on the exercise date. Participants may end their participation at any time during an offering period and will be paid their accrued contributions that have not yet been used to purchase shares of our common stock. Participation ends automatically upon termination of employment with us.

Non-Transferability. A participant may not transfer contributions credited to his or her account nor any rights granted under our 2021 ESPP other than by will, the laws of descent and distribution or as otherwise provided under our 2021 ESPP.

Merger or Change in Control. Our 2021 ESPP provides that in the event of a merger or change in control, as defined under our 2021 ESPP, a successor corporation (or a parent or subsidiary of the successor corporation) will assume or substitute each outstanding purchase right. If the successor corporation refuses to assume or substitute for the outstanding purchase right, the offering period with respect to which the purchase right relates will be shortened, and a new exercise date will be set that will be before the date of the proposed merger or change in control. The administrator will notify each participant that the exercise date has been changed and that the participant's option will be exercised automatically on the new exercise date unless prior to such date the participant has withdrawn from the offering period.

Amendment; Termination. The administrator will have the authority to amend, suspend or terminate our 2021 ESPP. Our 2021 ESPP automatically will terminate in 2041, unless we terminate it sooner.

401(k) Plan

We maintain a 401(k)-retirement savings plan for the benefit of our employees, including our named executive officers, who satisfy certain eligibility requirements. Under the 401(k) plan, eligible employees may elect to defer a portion of their compensation, within the limits prescribed by the Code, on a pre-tax or after-tax (Roth) basis, through contributions to the 401(k) plan. The 401(k) plan is intended to qualify under Sections 401(a) and 501(a) of the Code. As a tax-qualified retirement plan, pre-tax contributions to the 401(k) plan and earnings on those pre-tax contributions are not taxable to the employees until distributed from the 401(k) plan, and earnings on Roth contributions are not taxable when distributed from the 401(k) plan. We do not match contributions made by our employees or provide any other form of employer contributions, except as required by applicable law with respect to mandatory top-heavy contributions.

Limitation of Liability and Indemnification

Our amended and restated certificate of incorporation and bylaws, each to be effective upon the completion of this offering, will provide that we will indemnify our directors and officers, and may indemnify our employees and other agents, to the fullest extent permitted by Delaware law. Delaware law prohibits our amended and restated certificate of incorporation from limiting the liability of our directors for the following:

- any breach of the director's duty of loyalty to us or to our stockholders;
- acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law;
- unlawful payment of dividends or unlawful stock repurchases or redemptions; and
- any transaction from which the director derived an improper personal benefit.

If Delaware law is amended to authorize corporate action further eliminating or limiting the personal liability of a director, then the liability of our directors will be eliminated or limited to the fullest extent permitted by Delaware law, as so amended. Our amended and restated certificate of incorporation does not eliminate a director's duty of care and, in appropriate circumstances, equitable remedies, such as injunctive or other forms of non-monetary relief, remain available under Delaware law. This provision also does not affect a director's responsibilities under any other laws, such as the federal securities laws or other state or federal laws. Under our amended and restated bylaws, we will also be empowered to purchase insurance on behalf of any person whom we are required or permitted to indemnify.

In addition to the indemnification required in our amended and restated certificate of incorporation and bylaws, we have entered into an indemnification agreement with each member of our board of directors and each of our officers. These agreements provide for the indemnification of our directors and officers for certain expenses and liabilities incurred in connection with any action, suit, proceeding or alternative dispute resolution mechanism or hearing, inquiry or investigation that may lead to the foregoing, to which they are a party, or are threatened to be made a party, by reason of the fact that they are or were a director, officer, employee, agent

or fiduciary of our company, or any of our subsidiaries, by reason of any action or inaction by them while serving as an officer, director, agent or fiduciary, or by reason of the fact that they were serving at our request as a director, officer, employee, agent or fiduciary of another entity. In the case of an action or proceeding by or in the right of our company or any of our subsidiaries, no indemnification will be provided for any claim where a court determines that the indemnified party is prohibited from receiving indemnification. We believe that these amended and restated certificate of incorporation and bylaw provisions and indemnification agreements are necessary to attract and retain qualified persons as directors and officers.

The limitation of liability and indemnification provisions in our amended and restated certificate of incorporation and bylaws may discourage stockholders from bringing a lawsuit against directors for breach of their fiduciary duties. They may also reduce the likelihood of derivative litigation against directors and officers, even though an action, if successful, might benefit us and our stockholders. Moreover, a stockholder's investment may be harmed to the extent we pay the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions. Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers and controlling persons pursuant to the foregoing provisions, or otherwise, we have been advised that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act, and is, therefore, unenforceable. There is no pending litigation or proceeding naming any of our directors or officers as to which indemnification is being sought, nor are we aware of any pending or threatened litigation that may result in claims for indemnification by any director or officer.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

Other than compensation and indemnification arrangements with our directors and executive officers, including those discussed in the sections titled "Management" and "Executive Compensation," and the registration rights described in the section titled "Description of Capital Stock—Registration Rights," the following is a description of each transaction since January 1, 2018 and each currently proposed transaction in which:

- we have been or are to be a participant;
- the amount involved exceeded or exceeds $120,000; and
- any of our directors, executive officers or holders of more than 5% of our outstanding capital stock, or any immediate family member of, or person sharing the household with, any of these individuals or entities, had or will have a direct or indirect material interest.

Vimalan Asset Purchase Agreement

In February 2019, we entered into an asset purchase agreement, or the Vimalan Asset Purchase Agreement, with Vimalan Biosciences, Inc. (Vimalan). Pursuant to the Vimalan Asset Purchase Agreement, we purchased any and all of Vimalan's intellectual property related to inhibition of TYK2. Vimalan is beneficially owned by Raju Mohan, Ph.D., our chief executive officer, Christopher Krueger, our chief business officer, John Nuss, our chief scientific officer. NSV 2018 New Horizons, LP, NSV Investments I, LP, NSV 2019 Opportunities Fund, LP, and NSV Management, LLC hold simple agreements for future equity in Vimalan. NSV 2018 New Horizons, LP, NSV Investments I, LP, NSV 2019 Opportunities Fund, LP, and NSV Management, LLC are affiliated with both Somasundaram Subramaniam, our non-employee director, and are each holders of our capital stock.

Kalika Employment Arrangement

In January 2019, we entered into the Kalika Services Agreement with Kalika, pursuant to which Kalika provided certain administrative, research and development support services to us, in exchange for a monthly fee. Kalika entered into similar agreements with our subsidiaries Oppilan and Zomagen. In March 2021, the Kalika Services Agreements between Kalika and each of us, Oppilan and Zomagen were terminated. Kalika is beneficially owned by Raju Mohan, Ph.D., our chief executive officer, and NSV Management LLC, which is affiliated with both Somasundaram Subramaniam, our non-employee director, and funds of New Science Ventures, which are beneficial owners of more than 5% of our capital stock.

Oppilan Share Acquisition Agreement

In February 2021, we entered into a share purchase agreement, or the Oppilan Share Purchase Agreement, with Oppilan and the shareholders of Oppilan. Pursuant to the Oppilan Share Purchase Agreement, we purchased all of the issued and outstanding shares of Oppilan and substituted all of the outstanding options to purchase shares of Oppilan for options to purchase shares of our common stock. Raju Mohan, Ph.D., our chief executive officer, Christopher Krueger, J.D., M.B.A., our chief business officer, and Jigar Choksey, M.B.A. and Somasundaram Subramaniam, M.B.A., two of our non-employee directors, were directors of Oppilan at the time the transactions contemplated by the Oppilan Share Purchase Agreement were consummated. Each of Dr. Mohan, Mr. Krueger, and Dr. Nuss, our chief scientific officer, received the following shares of our common stock and our options to purchase shares of common stock in connection with the Oppilan Share Purchase Agreement:

NAME	COMMON STOCK	OPTIONS
Raju Mohan, Ph.D.	1,703,027	76,254
Christopher Krueger, J.D., M.B.A.	510,908	76,254
John Nuss, Ph.D.	340,606	76,254

Additionally, in connection with the Oppilan Share Purchase Agreement, (i) funds affiliated with New Science Ventures, which are holders of more than 5% of our outstanding capital stock and Mr. Subramaniam, a non-employee director, received 18,706,673 shares of our Series A-1 preferred stock and (ii) Third Point Ventures LLC, a holder of more than 5% of our outstanding capital stock and affiliate of Mr. Choksey, a non-employee director, received 20,020,953 shares of our Series A-1 preferred stock.

Zomagen Share Acquisition Agreement

In February 2021, we entered into a share purchase agreement, or the Zomagen Share Purchase Agreement, with Zomagen and the shareholders of Zomagen. Pursuant to the Zomagen Share Purchase Agreement, we purchased all of the issued and outstanding shares of Zomagen and substituted all of the outstanding options to purchase shares of Zomagen for options to purchase shares of our common stock. Dr. Mohan, Mr. Krueger, and Mr. Subramaniam, one of our non-employee directors, were directors of Zomagen at the time the transactions contemplated by the Zomagen Share Purchase Agreement were consummated. Each of Dr. Mohan, Mr. Krueger, and Dr. Nuss received the following shares of our common stock in connection with the Zomagen Share Purchase Agreement:

NAME	COMMON STOCK
Raju Mohan, Ph.D.	2,028,379
Christopher Krueger, J.D., M.B.A.	316,934
John Nuss, Ph.D.	760,642

Additionally, in connection with the Zomagen Share Purchase Agreement, funds affiliated with New Science Ventures, which are holders of more than 5% of our outstanding capital stock and Mr. Subramaniam, a non-employee director, received 19,164,836 shares of our Series A-1 preferred stock.

Convertible Instrument Financings

From February 2019 to December 2020, we issued and sold in private placements to various affiliated entities of New Science Ventures (i) convertible promissory notes, or NSV Notes, in an aggregate amount equal to $3.7 million, which such NSV Notes did not bear any interest, and (ii) simple agreements for future equity, or 2020 SAFEs, in an aggregate amount equal to $6.1 million. In January 2021, we issued and sold in a private placement a simple agreement for future equity, or the 2021 SAFE, to NSV Investments I, LP, in an aggregate amount equal to $0.5 million. The NSV Notes and 2020 SAFEs were converted into shares of our Series A-1 convertible preferred stock in February 2021. The 2021 SAFE was automatically converted into shares of our Series A convertible preferred stock in the February 2021 Series A convertible preferred stock financing, described below. Entities affiliated with New Science Ventures are beneficial owners of more than 5% of our capital stock. In addition, Mr. Subramaniam, a non-employee director, is affiliated with New Science Ventures.

Series A Preferred Stock Financing

Between February 2021 and June 2021, we issued and sold an aggregate of 119,879,441 shares of our Series A preferred stock at a purchase price of $0.9534578 per share for an aggregate purchase price of approximately $114.3 million (including the conversion of a simple agreement for future equity in an aggregate amount of $0.5 million). These shares of Series A preferred stock will convert into an aggregate of 119,879,441 shares of common stock upon the completion of this offering. The table below sets forth the number of shares of Series A preferred stock sold to our directors and holders of more than 5% of our capital stock:

INVESTOR	AFFILIATED DIRECTOR(S) OR OFFICER (S)	SHARES OF SERIES A PREFERRED STOCK	TOTAL PURCHASE PRICE ($)
Entities affiliated with New Science Ventures	Somasundaram Subramaniam	2,097,627	1,999,999
Sheila Gujrathi, M.D.	—	314,644	299,999
Third Point Ventures LLC	Jigar Choksey	8,390,512	7,999,999
venBio Global Strategic Fund III, L.P.	Aaron Royston; Richard Gaster	31,464,422	29,999,999

In connection with the Series A preferred stock financing, we entered into a restricted stock issuance agreement, or Issuance Agreement, with venBio SPV III, LLC, or venBio SPV. Pursuant to the Issuance Agreement, we issued venBio SPV 1,222,699 shares of our common stock as consideration for a portion of the purchase price paid to us by venBio Global Strategic Fund III, L.P., or venBio III, for the Series A preferred stock discussed above. venBio SPV is affiliated with (i) venBio III, a holder of more than 5% of our capital stock and (ii) Richard Gaster and Aaron Royston, two of our non-employee directors.

Investor Rights Agreement

We are party to an investor rights agreement with certain holders of our capital stock, including (i) Sheila Gujrathi, M.D., (ii) entities affiliated with New Science Ventures, (iii) Third Point Ventures LLC, and (iv) venBio III. Under our investor rights agreement, certain holders of our capital stock have the right to purchase shares in this offering, demand that we file a registration statement or request that their shares of our capital stock be covered by a registration statement that we are otherwise filing. See the section titled "Description of Capital Stock—Registration Rights" for additional information regarding these registration rights.

Voting Agreement

We are party to a voting agreement with certain holders of our capital stock, including (i) Dr. Gujrathi, (ii) entities affiliated with New Science Ventures, (iii) Third Point Ventures LLC, (iv) entities affiliated with venBio Partners, (v) Dr. Mohan, (vi) Mr. Krueger, and (vii) Dr. Nuss. The parties to such voting agreement have agreed, subject to certain conditions, to vote the shares of our capital stock held by them so as to elect the following individuals as directors: (1) two individuals designated by venBio III, currently Dr. Gaster and Dr. Royston, (2) one individual designated by NSV Investments I, LP, currently Mr. Subramaniam, (3) one individual designated by Third Point Ventures LLC, currently Mr. Choksey, (4) one individual designated by the holders a majority of the outstanding shares of common stock, who is currently Dr. Mohan, and (5) two individuals nominated by a majority of the other directors, voting together, currently Dr. Gujrathi and Mr. White. Upon the completion of this offering, the obligations of the parties to the voting agreement to vote their shares so as to elect these nominees, as well as the other rights and obligations under such voting agreement, will terminate and none of our stockholders will have any special rights regarding the nomination, election or designation of members of our board of directors.

Right of First Refusal and Co-Sale Agreement

We are party to a right of first refusal and co-sale agreement with certain holders of our capital stock, including (i) Dr. Gujrathi, (ii) entities affiliated with New Science Ventures, (iii) Third Point Ventures LLC, (iv) entities affiliated with venBio Partners, (v) Dr. Mohan, (vi) Mr. Krueger, and (vii) Dr. Nuss. Upon the completion of this offering, the rights and obligations of the parties to the right of first refusal and co-sale agreement will terminate.

Founders' Equity Grants

We have issued and sold shares of our common stock and granted options to our executive officers and certain of our non-employee directors as more fully described in the sections titled "Director Compensation" and "Executive Compensation."

Employment Agreements

We have entered into an employment agreement with Dr. Mohan, our chief executive officer. For more information regarding these employment agreements, see the section titled "Executive Compensation—Employment Arrangements with our Named Executive Officers."

Executive Chairperson Agreement

In May 2021, we entered into an executive chairperson agreement, or Chairperson Agreement, with Dr. Gujrathi, a non-employee director, to serve as our executive chairperson. In connection with her services, Dr. Gujrathi will receive an annual payment of $125,000 and was granted an option to purchase 7,291,605 shares of our common stock. Additionally, following the completion of this offering and subject to Dr. Gujrathi's continued status as a service provider, Dr. Gujrathi will be granted an option to purchase shares of our common stock in an amount equal to 0.5% of our fully diluted capitalization. In the event Dr. Gujrathi's service is terminated by us without cause or by Dr. Gujrathi for good reason, Dr. Gujrathi's outstanding options shall immediately become vested and exercisable with respect to that number of options which would have become vested and exercisable had Dr. Gujrathi remained our service provider for an additional twelve months following her termination.

Director and Officer Indemnification

We have entered into indemnification agreements with each of our directors and executive officers. These agreements, among other things, require us or will require us to indemnify each director (and in certain cases their related venture capital funds) and executive officer to the fullest extent permitted by Delaware law, including indemnification of expenses such as attorneys' fees, judgments, fines and settlement amounts

incurred by the director or executive officer in any action or proceeding, including any action or proceeding by or in right of us, arising out of the person's services as a director or executive officer.

Our amended and restated certificate of incorporation and our amended and restated bylaws will provide that we will indemnify each of our directors and officers to the fullest extent permitted by the Delaware General Corporation Law. Further, we have purchased a policy of directors' and officers' liability insurance that insures our directors and officers against the cost of defense, settlement or payment of a judgment under certain circumstances. For further information, see section titled "Executive Compensation—Limitations of Liability and Indemnification."

Stock Option Grants to Executive Officers and Directors

We have granted stock options to our executive officers and certain of our directors as more fully described in the section titled "Executive Compensation."

Related-Person Transactions Policy

We intend to adopt a formal, written policy, which will become effective on the date of effectiveness of the registration statement of which this prospectus forms a part, that our executive officers, directors (including director nominees), holders of more than 5% of any class of our voting securities and any member of the immediate family of or any entities affiliated with any of the foregoing persons, are not permitted to enter into a related-person transaction with us without the prior approval or, in the case of pending or ongoing related-person transactions, ratification of our audit committee. For purposes of our policy, a related-person transaction is a transaction, arrangement or relationship where we were, are or will be involved and in which a related-person had, has or will have a direct or indirect material interest.

Certain transactions with related persons, however, are exempted from pre-approval including, but not limited to:

- compensation of our executive officers and directors that is otherwise disclosed in our public filings with the SEC;
- compensation, benefits and other transactions available to all of our employees generally;
- transactions where a related-person's interest derives solely from his or her service as a director of another entity that is a party to the transaction;
- transactions where a related-person's interest derives solely from his or her ownership of less than 10% of the equity interest in another entity that is a party to the transaction; and
- transactions where a related-person's interest derives solely from his or her ownership of a class of our equity securities and all holders of that class received the same benefit on a pro rata basis.

No member of the audit committee may participate in any review, consideration or approval of any related-person transaction where such member or any of his or her immediate family members is the related-person. In approving or rejecting the proposed agreement, our audit committee shall consider the relevant facts and circumstances available and deemed relevant to the audit committee, including, but not limited to:

- the benefits and perceived benefits to us;
- the materiality and character of the related-person's direct and indirect interest;
- the availability of other sources for comparable products or services;
- the terms of the transaction; and
- the terms available to or from unrelated third parties under the same or similar circumstances.

PRINCIPAL STOCKHOLDERS

The following table sets forth the beneficial ownership of our common stock as of June 30, 2021 by:

- each person, or group of affiliated persons, who is known by us to beneficially own more than 5% of our common stock;
- each of the named executive officers;
- each of our directors; and
- all of our current executive officers and directors as a group.

We have determined beneficial ownership in accordance with the rules of the SEC, and thus it represents sole or shared voting or investment power with respect to our securities. Unless otherwise indicated below, to our knowledge, the persons and entities named in the table have sole voting and sole investment power with respect to all shares that they beneficially owned, subject to community property laws where applicable. The information does not necessarily indicate beneficial ownership for any other purpose, including for purposes of Sections 13(d) and 13(g) of the Exchange Act.

We have based our calculation of the percentage of beneficial ownership prior to this offering on shares of our common stock outstanding as of June 30, 2021, which includes shares of our common stock resulting from the conversion of all outstanding shares of our convertible preferred stock as of June 30, 2021 into our common stock immediately prior to the completion of this offering, as if this conversion had occurred as of June 30, 2021. We have based our calculation of the percentage of beneficial ownership after this offering on shares of our common stock outstanding immediately after the completion of this offering, assuming no exercise by the underwriters of their option to purchase additional shares. We have deemed shares of our common stock subject to stock options that are currently exercisable or exercisable within 60 days of June 30, 2021, to be outstanding and to be beneficially owned by the person holding the stock option for the purpose of computing the percentage ownership of that person. We did not deem these shares outstanding, however, for the purpose of computing the percentage ownership of any other person.

Except as noted below, the address for each person or entity listed in the table is c/o Ventyx Biosciences, Inc., 662 Encinitas Boulevard, Suite 250, Encinitas, CA 92024.

	SHARES BENEFICIALLY OWNED PRIOR TO THIS OFFERING		SHARES BENEFICIALLY OWNED AFTER THIS OFFERING	
NAME OF BENEFICIAL OWNER	SHARES	PERCENTAGE	SHARES	PERCENTAGE
5% or Greater Stockholders:				
Entities affiliated with New Science Ventures(1)				
Entities affiliated with venBio Partners(2)				
Third Point Ventures LLC(3)				
Raju Mohan, Ph.D.(4)				
Named Executive Officers and Directors:				
Raju Mohan, Ph.D.(5)				
Christopher Krueger, M.B.A.(6)				
John Nuss, Ph.D.(7)				
Martin Auster, M.D.				
Sheila Gujrathi, M.D.(8)				
Aaron Royston, M.D., M.B.A.				
Richard Gaster, M.D., Ph.D.				
Jigar Choksey, M.B.A.				
Somasundaram Subramaniam, M.B.A.				
William White, J.D., M.P.P.				
All executive officers and directors as a group (10 persons)(9)				

* Represents beneficial ownership of less than one percent (1%) of the outstanding shares of our common stock.

(1) Consists of (i) shares of Series A preferred stock held by NSV Investments I, LP, and (ii) shares of Series A-1 preferred stock held by NSV Investments I, LP, NSV Master Limited Partnership II, LP, NSV 2019 Opportunities Fund, LP, NSV 2018 New Horizons Fund, LP, Life & Tech, NSV Investments II, LP, NSV Investments III, LP, New Science Ventures Fund III, LP, New Science Ventures, LLC, NSV Growth Opportunities Fund, LP, NSV 2017 Opportunities Fund, LP, NSV 2018

Opportunities Fund, LP, NSV 2016 Opportunities Fund, LP, New Science Ventures Fund III (Offshore), LP, or NSV 2016 Opportunities Fund (Offshore), LP, or the NSV Funds. NSV Management, LLC is the investment advisor to Life & Tech. NSV Partners II, LLC, is the general partner of New Science Ventures Fund III, LP, New Science Ventures Fund III (Offshore), LP, NSV 2016 Opportunities Fund, LP, NSV 2016 Opportunities Fund (Offshore), LP, NSV 2017 Opportunities Fund, LP, and NSV Master Limited Partnership II, LP. Mr. Subramaniam is the majority member and managing member NSV Partners II, LLC, and may be deemed to have voting and dispositive power over the shares held by each entity of which NSV Partners II, LLC is general partner. NSV Partners III, LP, is the general partner of NSV 2018 New Horizons Fund LP, NSV Investments I, LP, NSV 2018 Opportunities Fund, LP, NSV 2019 Opportunities Fund, LP, NSV Growth Opportunities Fund, LP, NSV Investments III, LP, and NSV Investments II, LP. NSV Partners III GP, LLC is the general partner of NSV Partners III, LP. Mr. Subramaniam is the majority member and managing member of NSV Partners III GP, LLC, and may be deemed to have voting and dispositive power over the shares held by each entity of which NSV Partners III, LP is general partner. Mr. Subramaniam disclaims beneficial ownership over the shares held by each of the NSV funds, except to the extent of his pecuniary interest therein. The address of the NSV Funds is 299 Park Avenue, 41st Floor, New York, NY 10171.

(2) Consists of (i) shares of Series A preferred stock held by venBio Global Strategic Fund III, L.P., or venBio III, and (ii) shares of common stock held by venBio SPV III, LLC, or venBio SPV. Aaron Royston and Richard Gaster are members of our board of directors and partners at venBio Partners. Richard Gaster has no voting or dispositive power over the shares held by venBio III and venBio SPV. venBio SPV is wholly-owned and managed by venBio III. venBio Global Strategic GP III, L.P., a Cayman Islands partnership, or venBio GP, is the sole general partner of venBio III. venBio Global Strategic GP III, Ltd., a Cayman Islands company, or venBio Ltd, the sole general partner of venBio GP. Aaron Royston, Robert Adelman and Corey Goodman, or the Directors, are each a director of venBio Ltd and may be deemed to share voting and dispositive power over the shares held by venBio III, venBio SPV, venBio GP and venBio Ltd. Each of the Directors, together with venBio Ltd and venBio GP, disclaims beneficial ownership over the shares held by venBio III and venBio SPV except to the extent of their pecuniary interest therein. The address of each of the above persons and entities is 1700 Owens Street Suite 595 San Francisco, CA 94158.

(3) Consists of (i) shares of Series A preferred stock and (ii) shares of Series A-1 preferred stock held of record by Third Point Ventures LLC, as nominee for funds managed and/or advised by Third Point LLC. Third Point LLC and Daniel S. Loeb, managing member of Third Point LLC, may be deemed to have voting and investment power of such shares. The address for each of these entities is 55 Hudson Yards, New York, NY 10001.

(4) Consists of (i) shares of common stock and (ii) shares of common stock underlying options held by Dr. Mohan that are exercisable as of June 30, 2021 or that will become exercisable within 60 days after such date.

(5) Consists of the shares described in note 4 above.

(6) Consists of (i) shares of common stock, including shares subject to forfeiture and (ii) shares of common stock underlying options held by Mr. Krueger that are exercisable as of June 30, 2021 or that will become exercisable within 60 days after such date.

(7) Consists of (i) shares of common stock, including shares subject to forfeiture and (ii) shares of common stock underlying options held by Dr. Nuss that are exercisable as of June 30, 2021 or that will become exercisable within 60 days after such date.

(8) Consists of shares of Series A preferred stock.

(9) Consists of the shares described in notes 5 through 8 above.

DESCRIPTION OF CAPITAL STOCK

General

The following descriptions of our capital stock and certain provisions of our amended and restated certificate of incorporation and the amended and restated bylaws are summaries and are qualified by reference to the amended and restated certificate of incorporation and the amended and restated bylaws that will be in effect upon completion of this offering. Copies of these documents will be filed with the SEC as exhibits to our registration statement, of which this prospectus forms a part. The descriptions of the common stock and preferred stock reflect changes to our capital structure that will occur upon the completion of this offering.

Following the completion of this offering and the filing of our amended and restated certificate of incorporation to be effective immediately prior to this offering, our authorized capital stock will consist of shares of common stock, par value $0.0001 per share, and shares of convertible preferred stock, par value $0.0001 per share.

Immediately prior to the completion of this offering, all the outstanding shares of our convertible preferred stock will automatically convert into an aggregate of shares of our common stock.

Common Stock

Outstanding Shares

Based on shares of common stock outstanding as of June 30, 2021, and after giving effect to the automatic conversion of all of our outstanding shares of convertible preferred stock as of June 30, 2021 into an aggregate of shares of common stock upon the completion of this offering and the issuance of shares of common stock in this offering, and assuming no exercise of the underwriters' option to purchase additional shares and no exercise of options, there will be shares of common stock outstanding upon the completion of this offering. As of June 30, 2021, we had approximately 24 record holders of our common stock.

Voting Rights

Each holder of common stock is entitled to one vote per share on all matters (including the election of directors) submitted to a vote of the stockholders. Our amended and restated certificate of incorporation and amended and restated bylaws to be in effect upon the completion of this offering do not provide for cumulative voting rights. Because of this, the holders of a plurality of the shares of common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they should so choose. With respect to matters other than the election of directors, at any meeting of the stockholders at which a quorum is present or represented, the affirmative vote of a majority of the voting power of the shares present in person or represented by proxy at such meeting and entitled to vote on the subject matter shall be the act of the stockholders, except as otherwise required by law. The holders of a majority of the stock issued and outstanding and entitled to vote, present in person or represented by proxy, shall constitute a quorum for the transaction of business at all meetings of the stockholders.

Dividends

Subject to preferences that may be applicable to any then-outstanding convertible preferred stock, holders of our common stock are entitled to receive dividends, if any, as may be declared from time to time by our board of directors out of legally available funds. For more information see the section titled "Dividend Policy."

Liquidation

In the event of our liquidation, dissolution or winding up, holders of our common stock and convertible preferred stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities and the satisfaction of any liquidation preference granted to the holders of any then-outstanding shares of convertible preferred stock.

Rights and Preferences

Holders of our common stock have no preemptive, conversion, subscription or other rights, and there are no redemption or sinking fund provisions applicable to our common stock. The rights, preferences and privileges of the holders of our common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of our convertible preferred stock that we may designate in the future.

Fully Paid and Nonassessable

All of our outstanding shares of common stock are, and the shares of common stock to be issued in this offering, upon payment and delivery in accordance with the underwriting agreement, will be, fully paid and nonassessable.

Preferred Stock

Upon the completion of this offering, our board of directors will have the authority, without further action by the stockholders, to issue up to shares of convertible preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions thereof. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, redemption rights, liquidation preferences, sinking fund terms and the number of shares constituting any series or the designation of such series, any or all of which may be greater than the rights of common stock. The issuance of convertible preferred stock could adversely affect the voting power of holders of common stock and the likelihood that such holders will receive dividend payments and payments upon liquidation. In addition, the issuance of convertible preferred stock could have the effect of delaying, deferring or preventing change in our control or other corporate action. Upon completion of this offering, no shares of convertible preferred stock will be outstanding, and we have no present plan to issue any shares of convertible preferred stock.

Options

As of June 30, 2021, options to purchase shares of our common stock were outstanding, with a weighted-average exercise price of $ per share under our 2019 Plan. For additional information regarding the terms of our 2019 Plan, see the section titled “Executive Compensation—Employee Benefit and Stock Plans—2019 Equity Incentive Plan.”

Registration Rights

Upon the completion of this offering holders of shares of our common stock, which includes all of the shares of common stock issuable upon the automatic conversion of our convertible preferred stock immediately prior to the completion of this offering, will be entitled to the rights described below with respect to the registration of such shares for public resale under the Securities Act, pursuant to the investor rights agreement by and among us and certain of our stockholders. The registration of shares of common stock as a result of the following rights being exercised would enable holders to trade these shares without restriction under the Securities Act when the applicable registration statement is declared effective.

Demand Registration Rights

At any time beginning six months following the completion of this offering, the holders of at least fifty percent (50%) of the shares having demand registration rights have the right to demand that we file a registration statement for the registration of the offer and sale of such shares, so long as the anticipated aggregate net offering price is greater than $15.0 million. We are not obligated to file any registration statements within 60 days before the filing date of, or within 180 days after the effective date of, a registration statement that we propose. These registration rights are subject to specified conditions and limitations, including the right of the underwriters to limit the number of shares included in any such registration under certain circumstances and our ability to defer the filing of a registration statement with respect to an exercise of such demand registration rights for up to 60 days under certain circumstances. We are obligated to effect at most two registrations for the holders of registrable securities in response to these demand registration rights, subject to certain exceptions.

Form S-3 Registration Rights

At any time after we are qualified to file a registration statement on Form S-3, the holders of at least twenty percent (20%) of the shares having demand registration rights have the right to demand that we file a registration statement on Form S-3 so long as the aggregate number of shares to be offered and sold under such registration statement on Form S-3 is at least $5.0 million. We are not obligated to file any registration statements within 30 days before the filing date of, or within 90 days after the effective date, of a registration statement that we propose. These investor registration rights are subject to specified conditions and limitations, including our ability to defer the filing of a registration statement with respect to an exercise of such Form S-3 registration rights for up to 60 days under certain circumstances.

Piggyback Registration Rights

At any time immediately prior to the completion of this offering, if we propose to register the offer and sale of any of our securities under the Securities Act either for our own account or for the account of other stockholders, a stockholder with registration rights will have the right, subject to certain exceptions, to include their shares of common stock in the registration statement. These registration rights are subject to specified conditions and limitations, and any proposed offering in connection therewith may be terminated or withdrawn by us at our sole discretion.

Expenses of Registration

We will pay all expenses relating to any demand registrations, Form S-3 registrations and piggyback registrations, other than underwriting discounts and selling commissions and up to $75,000 of fees and disbursements of one counsel to the selling stockholders.

Termination of Registration Rights

The registration rights terminate upon the earlier of: (1) three years after the completion of this offering, (2) upon the closing of an acquisition of our company or (3) with respect to a particular holder, such time as Rule 144 or another similar exemption under the Securities Act is available for the sale of all shares by such holder without limitation during a three-month period without registration.

Anti-Takeover Effects of Delaware Law and Our Certificate of Incorporation and Bylaws

Provisions of our amended and restated certificate of incorporation and amended and restated bylaws may delay or discourage transactions involving an actual or potential change in our control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares, or transactions that our stockholders might otherwise deem to be in their best interests. Therefore, these provisions could adversely affect the price of our common stock. Among other things, our amended and restated certificate of incorporation and amended and restated bylaws will:

- permit our board of directors to issue up to shares of convertible preferred stock, with any rights, preferences and privileges as they may designate, including the right to approve an acquisition or other change in our control;
- provide that the authorized number of directors may be changed only by resolution of the board of directors, subject to the rights of any holders of convertible preferred stock;
- provide that all vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide notice in writing in a timely manner, and also meet specific requirements as to the form and content of a stockholder's notice;
- not provide for cumulative voting rights (therefore allowing the holders of a plurality of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose);
- provide that special meetings of our stockholders may be called only by the board of directors, the chairman of the board of directors, our chief executive officer or president (in the absence of a chief executive officer);
- provide that stockholders will be permitted to amend certain provisions of our bylaws only upon receiving at least two-thirds of the votes entitled to be cast by holders of all outstanding shares then entitled to vote generally in the election of directors, voting together as a single class; and
- provide that, unless we otherwise consent in writing, a state or federal court located within the State of Delaware shall be the sole and exclusive forum for (1) any derivative action or proceeding brought on behalf of the company, (2) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to the company or our stockholders, (3) any action asserting a claim against the company arising pursuant to any provision of the Delaware General Corporation Law, or (4) any action asserting a claim against the company governed by the internal affairs doctrine.

The amendment of any of these provisions would require approval by the holders of at least two-thirds of our then outstanding common stock, voting as a single class.

Our amended and restated certificate of incorporation will provide that, unless we consent to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a claim of breach of fiduciary duty, any action asserting a claim arising pursuant to the Delaware General Corporation Law, any action regarding our amended and restated certificate of incorporation or our amended and restated bylaws, or any action asserting a claim against us that is governed by the internal affairs doctrine. Our amended and restated certificate of incorporation will provide further that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act.

Listing

We intend to apply to have our common stock approved for listing on the Nasdaq Global Market under the trading symbol “VTYX.”

Transfer Agent and Registrar

Upon completion of this offering, the transfer agent and registrar for our common stock will be . The transfer agent and registrar’s address is , and its telephone number is .

SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no public market for our common stock, and although we expect that our common stock will be approved for listing on the Nasdaq Global Market, we cannot assure you that there will be an active public market for our common stock following this offering. We cannot predict what effect sales of our shares in the public market or the availability of shares for sale will have on the market price of our common stock. Future sales of substantial amounts of common stock in the public market, including shares issued upon exercise of outstanding options, or the perception that such sales may occur, however, could adversely affect the market price of our common stock and also could adversely affect our future ability to raise capital through the sale of our common stock or other equity-related securities at times and prices we believe appropriate.

Upon completion of this offering, based on our shares outstanding as of June 30, 2021 and after giving effect to the automatic conversion of all outstanding shares of our convertible preferred stock, shares of our common stock will be outstanding, or shares of common stock if the underwriters exercise in full their option to purchase additional shares. All of the shares of common stock expected to be sold in this offering will be freely tradable without restriction or further registration under the Securities Act unless held by our "affiliates," as that term is defined in Rule 144 under the Securities Act. The remaining outstanding shares of our common stock will be deemed "restricted securities" as that term is defined under Rule 144. Restricted securities may be sold in the public market only if their offer and sale is registered under the Securities Act or if the offer and sale of those securities qualify for an exemption from registration, including exemptions provided by Rules 144 and 701 under the Securities Act, which are summarized below.

As a result of the lock-up agreements and market stand-off provisions described below and the provisions of Rules 144 or 701, and assuming no extension of the lock-up period and no exercise of the underwriters' option to purchase additional shares, the shares of our common stock that will be deemed "restricted securities" will be available for sale in the public market following the completion of this offering as follows:

- shares will be eligible for sale on the date of this prospectus; and
- shares will be eligible for sale upon expiration of the lock-up agreements and market stand-off provisions described below, beginning more than 180 days after the date of this prospectus.

We may issue shares of our common stock from time to time for a variety of corporate purposes, including in capital-raising activities through future public offerings or private placements, in connection with exercise of stock options or warrants, vesting of restricted stock units and other issuances relating to our employee benefit plans and as consideration for future acquisitions, investments or other purposes. The number of shares of our common stock that we may issue may be significant, depending on the events surrounding such issuances. In some cases, the shares we issue may be freely tradable without restriction or further registration under the Securities Act; in other cases, we may grant registration rights covering the shares issued in connection with these issuances, in which case the holders of our common stock will have the right, under certain circumstances, to cause us to register any resale of such shares to the public.

Lock-Up Agreements and Market Standoff Provisions

In connection with this offering, we, our officers, directors and the holders of substantially all of our securities have entered into or will enter into lock-up agreements with the underwriters, among other things and subject to certain exceptions, not to dispose of or hedge any of their common stock or securities convertible into or exchangeable for shares of common stock during the period from the date of this prospectus continuing through the date 180 days after the date of this prospectus, except with the prior consent of Jefferies LLC, Evercore Group L.L.C. and Piper Sandler & Co.. See the section titled "Underwriting" for additional information.

In addition to the restrictions contained in the lock-up agreements described above, our officers, directors and the holders of substantially all of our capital stock and options have entered into market stand-off agreements with us.

Rule 144

In general, under Rule 144, beginning 90 days after the effective date of this prospectus, a person who is not our affiliate for purposes of the Securities Act and has not been our affiliate at any time during the preceding three months will be entitled to sell any shares of our common stock that such person has beneficially owned for at least six months, including the holding period of any prior owner other than one of our affiliates, without being required to comply with the notice, manner of sale or public information requirements or volume limitation

provisions of Rule 144. Sales of our common stock by any such person would be subject to the availability of current public information about us if the shares to be sold were beneficially owned by such person for less than one year.

In addition, under Rule 144, a person may sell shares of our common stock acquired from us immediately upon the completion of this offering, without regard to the registration requirements of the Securities Act or the availability of public information about us, if:

- the person is not our affiliate and has not been our affiliate at any time during the preceding three months; and
- the person has beneficially owned the shares to be sold for at least one year, including the holding period of any prior owner other than one of our affiliates.

Beginning 90 days after the date of this prospectus, our affiliates who have beneficially owned shares of our common stock for at least six months, including the holding period of any prior owner other than one of our affiliates, would be entitled to sell within any three-month period a number of shares that does not exceed the greater of:

- 1% of the number of shares of our common stock then outstanding, which will equal approximately shares immediately after this offering, assuming no exercise of the underwriters' option to purchase additional shares; and
- the average weekly trading volume in our common stock on the Nasdaq Global Market during the four calendar weeks preceding the date of filing of a notice on Form 144 with respect to the sale.

Rule 701

Rule 701 generally provides that, once we have been subject to the public company reporting requirements of Section 13 or Section 15(d) of the Exchange Act for at least 90 days, a stockholder who purchased shares of our common stock pursuant to a written compensatory benefit plan or contract and who is not deemed to have been one of our affiliates at any time during the preceding 90 days may sell such shares (to the extent such shares are not subject to a lock-up agreement) in reliance upon Rule 144 without complying with the current public information or holding period conditions of Rule 144. Rule 701 also provides that a stockholder who purchased shares of our common stock pursuant to a written compensatory benefit plan or contract and who is deemed to have been one of our affiliates during the preceding 90 days may sell such shares under Rule 144 without complying with the holding period condition of Rule 144 (subject to the lock-up agreement referred to above, if applicable). However, all stockholders who purchased shares of our common stock pursuant to a written compensatory benefit plan or contract are required to wait until 90 days after the date of this prospectus before selling such shares pursuant to Rule 701 (subject to the lock-up agreement referred to above, if applicable).

Stock Options

As of June 30, 2020, options to purchase an aggregate of 15,821,529 shares of our common stock were outstanding. We intend to file one or more registration statements on Form S-8 under the Securities Act to register the offer and sale of all shares of our common stock subject to outstanding stock options and all shares issued or issuable under our stock plans. We expect to file the registration statement covering these shares after the date of this prospectus, which will permit the resale of such shares by persons who are non-affiliates of ours in the public market without restriction under the Securities Act, subject, with respect to certain of the shares, to the provisions of the lock-up agreements and market stand-off provisions described above.

Registration Rights

Upon completion of this offering, the holders of approximately shares of our common stock will be eligible to exercise certain rights to cause us to register their shares for resale under the Securities Act, subject to various conditions and limitations. These registration rights are described under the section titled "Description of Capital Stock—Registration Rights." Upon the effectiveness of a registration statement covering these shares, the shares would become freely tradable, and a large number of shares may be sold into the public market, which may adversely affect the market price of our common stock.

MATERIAL U.S. FEDERAL INCOME TAX CONSIDERATIONS FOR NON-U.S. HOLDERS OF OUR COMMON STOCK

The following is a summary of the material U.S. federal income tax consequences of the ownership and disposition of our common stock acquired in this offering by a "non-U.S. holder" (as defined below), but does not purport to be a complete analysis of all the potential tax considerations relating thereto. This summary is based upon the provisions of the Code, Treasury Regulations promulgated thereunder, administrative rulings and judicial decisions, all as of the date hereof. These authorities may be changed, possibly retroactively, so as to result in U.S. federal income tax consequences different from those set forth below. We have not sought, and do not intend to seek, any ruling from the Internal Revenue Service, or IRS, with respect to the statements made and the conclusions reached in the following summary, and there can be no assurance that the IRS or a court will agree with such statements and conclusions.

This summary does not address the tax considerations arising under the laws of any non-U.S., state or local jurisdiction or under U.S. federal gift and estate tax rules, nor does it address all aspects of U.S. federal income taxation that may be relevant to a particular non-U.S. holder in light of that non-U.S. holder's individual circumstances, including the alternative minimum tax, the tax on net investment income, or special tax accounting rules under Section 451(b) of the Code. In addition, this discussion does not address tax considerations applicable to an investor's particular circumstances or to investors that may be subject to special tax rules, including, without limitation:

- banks, insurance companies, regulated investment companies, real estate investment trusts or other financial institutions;
- tax-exempt organizations;
- pension plans and tax-qualified retirement plans;
- controlled foreign corporations, passive foreign investment companies and corporations that accumulate earnings to avoid U.S. federal income tax;
- brokers or dealers in securities or currencies;
- traders in securities that elect to use a mark-to-market method of accounting for their securities holdings;
- persons that own, or are deemed to own, more than five percent of our capital stock (except to the extent specifically set forth below);
- certain former citizens or long-term residents of the United States;
- persons who hold our common stock as a position in a hedging transaction, "straddle," "conversion transaction" or other risk reduction transaction;
- persons who do not hold our common stock as a capital asset within the meaning of Section 1221 of the Code (generally, property held for investment);
- persons deemed to sell our common stock under the constructive sale provisions of the Code; or
- persons who acquired our common stock as compensation or otherwise in connection with the performance of serves.

In addition, if a partnership, entity or arrangement classified as a partnership or flow-through entity for U.S. federal income tax purposes holds our common stock, the tax treatment of a partner generally will depend on the status of the partner and upon the activities of the partnership or other entity. A partner in a partnership or other such entity that will hold our common stock should consult his, her or its own tax advisor regarding the tax consequences of the ownership and disposition of our common stock through a partnership or other such entity, as applicable.

You are urged to consult your tax advisor with respect to the application of U.S. federal income tax laws to your particular situation, as well as any tax consequences of the purchase, ownership and disposition of our common stock arising under U.S. federal gift or estate tax rules or under the laws of any state, local, non-U.S. or other taxing jurisdiction or under any applicable tax treaty.

Non-U.S. Holder Defined

For purposes of this discussion, you are a "non-U.S. holder" if you are a beneficial owner of our common stock that, for U.S. federal income tax purposes, is not a partnership or:

- an individual who is a citizen or resident of the United States;
- a corporation or other entity taxable as a corporation created or organized in the United States or under the laws of the United States or any political subdivision thereof, or otherwise treated as such for U.S. federal income tax purposes;
- an estate whose income is subject to U.S. federal income tax regardless of its source; or
- a trust (1) whose administration is subject to the primary supervision of a U.S. court and that has one or more U.S. persons who have the authority to control all substantial decisions of the trust or (2) that has made a valid election under applicable Treasury Regulations to be treated as a U.S. person.

Distributions

As described in the section titled "Dividend Policy," we have never declared or paid cash dividends on our common stock, and we do not anticipate paying any dividends on our common stock following the completion of this offering. However, if we do make distributions on our common stock, those payments will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. To the extent those distributions exceed both our current and our accumulated earnings and profits, the excess will constitute a return of capital and will first reduce your basis in our common stock, but not below zero, and then will be treated as gain from the sale of stock.

Subject to the discussions below on effectively connected income, backup withholding and FATCA , any dividend paid to you generally will be subject to U.S. federal withholding tax either at a rate of 30% of the gross amount of the dividend or such lower rate as may be specified by an applicable income tax treaty between the United States and your country of residence. In order to receive a reduced treaty rate, you must provide the applicable withholding agent with an IRS Form W-8BEN or W-8BEN-E or other appropriate version of IRS Form W-8 certifying qualification for the reduced rate. A non-U.S. holder of shares of our common stock eligible for a reduced rate of U.S. federal withholding tax pursuant to an income tax treaty may be entitled to a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS. If the non-U.S. holder holds our common stock through a financial institution or other agent acting on the non-U.S. holder's behalf, the non-U.S. holder will be required to provide appropriate documentation to the agent, which then will be required to provide certification to the applicable withholding agent, either directly or through other intermediaries.

Dividends received by you that are treated as effectively connected with your conduct of a U.S. trade or business (and, if required by an applicable income tax treaty, that are attributable to a permanent establishment or fixed base maintained by you in the United States) are generally exempt from the 30% U.S. federal withholding tax, subject to the discussions below on backup withholding and FATCA. In order to obtain this exemption, you must provide the applicable withholding agent with a properly executed IRS Form W-8ECI or other applicable IRS Form W-8 properly certifying such exemption. Such effectively connected dividends, although not subject to U.S. federal withholding tax, are taxed at the same graduated rates applicable to U.S. persons, net of certain deductions and credits, subject to an applicable income tax treaty providing otherwise. In addition, if you are a corporate non-U.S. holder, dividends you receive that are effectively connected with your conduct of a U.S. trade or business may also be subject to a branch profits tax at a rate of 30% (unless an applicable income tax treaty between the United States and your country of residence provides for different treatment). You should consult your tax advisor regarding the tax consequences of the ownership and disposition of our common stock, including any applicable tax treaties that may provide for different rules.

Gain on Disposition of Common Stock

Subject to the discussions below regarding backup withholding and FATCA, you generally will not be required to pay U.S. federal income tax on any gain realized upon the sale or other disposition of our common stock unless:

- the gain is effectively connected with your conduct of a U.S. trade or business (and, if an applicable income tax treaty so provides, the gain is attributable to a permanent establishment or fixed base maintained by you in the United States);
- you are an individual who is present in the United States for a period or periods aggregating 183 days or more during the calendar year in which the sale or disposition occurs and certain other conditions are met; or
- our common stock constitutes a U.S. real property interest by reason of our status as a "United States real property holding corporation," or USRPHC, for U.S. federal income tax purposes at any time within the shorter of the five-year period preceding your disposition of, or your holding period for, our common stock.

We believe that we are not currently and will not become a USRPHC for U.S. federal income tax purposes, and the remainder of this discussion so assumes. However, because the determination of whether we are a USRPHC depends on the fair market value of our U.S. real property interests relative to the fair market value of our U.S. and worldwide real property interests plus our other business assets, there can be no assurance that we will not become a USRPHC in the future. Even if we become a USRPHC, however, as long as our common stock is "regularly traded" on an "established securities market," your common stock will be treated as U.S. real property interests only if you actually (directly or indirectly) or constructively hold more than five percent of such regularly traded common stock at any time during the shorter of the five-year period preceding your disposition of, or your holding period for, our common stock.

If you are a non-U.S. holder described in the first bullet above, you will be required to pay tax on the gain derived from the sale (net of certain deductions and credits) under regular U.S. federal income tax rates, and a corporate non-U.S. holder described in the first bullet above also may be subject to the branch profits tax at a 30% rate, or such lower rate as may be specified by an applicable income tax treaty. If you are an individual non-U.S. holder described in the second bullet above, you will be subject to tax at 30% (or such lower rate specified by an applicable income tax treaty) on the gain derived from the sale, which gain may be offset by U.S. source capital losses for the year, provided you have timely filed U.S. federal income tax returns with respect to such losses. You should consult your tax advisor regarding any applicable income tax or other treaties that may provide for different rules.

Federal Estate Tax

Our common stock beneficially owned by an individual who is not a citizen or resident of the United States (as defined for U.S. federal estate tax purposes) at the time of his or her death will generally be includable in the decedent's gross estate for U.S. federal estate tax purposes. Such stock, therefore, may be subject to U.S. federal estate tax, unless an applicable estate tax treaty provides otherwise.

Backup Withholding and Information Reporting

Generally, we must report annually to the IRS the amount of dividends paid to you, your name and address, and the amount of tax withheld, if any. A similar report will be sent to you. Pursuant to applicable income tax treaties or other agreements, the IRS may make these reports available to tax authorities in your country of residence.

Payments of dividends on or of proceeds from the disposition of our common stock made to you may be subject to information reporting and backup withholding (currently at a rate of 24%) unless you establish an exemption, for example, by properly certifying your non-U.S. status on a properly completed IRS Form W-8BEN or W-8BEN-E or another appropriate version of IRS Form W-8. Notwithstanding the foregoing, backup withholding and information reporting may apply if the applicable withholding agent has actual knowledge, or reason to know, that you are a U.S. person.

Backup withholding is not an additional tax; rather, the U.S. federal income tax liability of persons subject to backup withholding will be reduced by the amount of tax withheld. If withholding results in an overpayment of taxes, a refund or credit may generally be obtained from the IRS, provided that the required information is furnished to the IRS in a timely manner.

Foreign Account Tax Compliance Act (FATCA)

The Foreign Account Tax Compliance Act and the rules and regulations promulgated thereunder (collectively FATCA) generally impose a U.S. federal withholding tax of 30% on dividends on, and the gross proceeds from a sale or other disposition of, our common stock paid to a "foreign financial institution" (as specially defined under these rules), unless such institution enters into an agreement with the U.S. government to, among other things, withhold on certain payments and to collect and provide to the U.S. tax authorities substantial information regarding the U.S. account holders of such institution (which includes certain equity and debt holders of such institution, as well as certain account holders that are foreign entities with U.S. owners) or otherwise establishes an exemption. FATCA also generally imposes a U.S. federal withholding tax of 30% on dividends on, and the gross proceeds from a sale or other disposition of, our common stock paid to a "non-financial foreign entity" (as specially defined under these rules), unless such entity provides the withholding agent with a certification identifying the substantial direct and indirect U.S. owners of the entity, certifies that it does not have any substantial U.S. owners, or otherwise establishes an exemption.

The withholding obligations under FATCA generally apply to dividends on our common stock. The withholding tax will apply regardless of whether the payment otherwise would be exempt from U.S. nonresident and backup withholding tax, including under the other exemptions described above. Under certain circumstances, a non-U.S. holder might be eligible for refunds or credits of such taxes. The Treasury Department has released proposed Treasury Regulations (the preamble to which specifies that taxpayers are permitted to rely on them pending finalization) which, if finalized in their present form, would eliminate the withholding tax applicable to the gross proceeds of a disposition of our common stock. An intergovernmental agreement between the United States and an applicable foreign country may modify the requirements described in this section. Prospective investors are encouraged to consult with their own tax advisors regarding the application of FATCA withholding to their investment in, and ownership and disposition of, our common stock.

The preceding discussion of U.S. federal tax considerations is for general information only. It is not tax advice to investors in their particular circumstances. Each prospective investor should consult its own tax advisor regarding the particular U.S. federal, state and local and non-U.S. tax consequences of purchasing, holding and disposing of our common stock, including the consequences of any proposed change in applicable laws.

UNDERWRITING

Subject to the terms and conditions set forth in the underwriting agreement, dated , 2021, between us and Jefferies LLC, Evercore Group L.L.C. and Piper Sandler & Co., as the representatives of the underwriters named below and the joint book-running managers of this offering, we have agreed to sell to the underwriters, and each of the underwriters has agreed, severally and not jointly, to purchase from us, the respective number of shares of common stock shown opposite its name below:

UNDERWRITER	NUMBER OF SHARES
Jefferies LLC	
Evercore Group L.L.C.	
Piper Sandler & Co.	
LifeSci Capital LLC	
Total	

The underwriting agreement provides that the obligations of the several underwriters are subject to certain conditions precedent such as the receipt by the underwriters of officers' certificates and legal opinions and approval of certain legal matters by their counsel. The underwriting agreement provides that the underwriters will purchase all of the shares of common stock if any of them are purchased. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the nondefaulting underwriters may be increased or the underwriting agreement may be terminated. We have agreed to indemnify the underwriters and certain of their controlling persons against certain liabilities, including liabilities under the Securities Act, and to contribute to payments that the underwriters may be required to make in respect of those liabilities.

The underwriters have advised us that, following the completion of this offering, they currently intend to make a market in the common stock as permitted by applicable laws and regulations. However, the underwriters are not obligated to do so, and the underwriters may discontinue any market-making activities at any time without notice in their sole discretion. Accordingly, no assurance can be given as to the liquidity of the trading market for the common stock, that you will be able to sell any of the common stock held by you at a particular time or that the prices that you receive when you sell will be favorable.

The underwriters are offering the shares of common stock subject to their acceptance of the shares of common stock from us and subject to prior sale. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

Commission and Expenses

The underwriters have advised us that they propose to offer the shares of common stock to the public at the initial public offering price set forth on the cover page of this prospectus and to certain dealers, which may include the underwriters, at that price less a concession not in excess of $ per share of common stock. The underwriters may allow, and certain dealers may reallow, a discount from the concession not in excess of $ per share of common stock to certain brokers and dealers. After the offering, the initial public offering price, concession and reallowance to dealers may be reduced by the representatives. No such reduction will change the amount of proceeds to be received by us as set forth on the cover page of this prospectus.

The following table shows the public offering price, the underwriting discounts and commissions that we are to pay the underwriters and the proceeds, before expenses, to us in connection with this offering. Such amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase additional shares.

	PER SHARE		TOTAL	
	WITHOUT OPTION TO PURCHASE ADDITIONAL SHARES	WITH OPTION TO PURCHASE ADDITIONAL SHARES	WITHOUT OPTION TO PURCHASE ADDITIONAL SHARES	WITH OPTION TO PURCHASE ADDITIONAL SHARES
Public offering price	$	$	$	$
Underwriting discounts and commissions paid by us	$	$	$	$
Proceeds to us, before expenses	$	$	$	$

We estimate expenses payable by us in connection with this offering, other than the underwriting discounts and commissions referred to above, will be approximately $. We have also agreed to reimburse the underwriters for up to $ for their Financial Industry Regulatory Authority, Inc., or FINRA, counsel fee. In accordance with FINRA Rule 5110, this reimbursed fee is deemed underwriting compensation for this offering.

Determination of Offering Price

Prior to this offering, there has not been a public market for our common stock. Consequently, the initial public offering price for our common stock will be determined by negotiations between us and the representatives. Among the factors to be considered in these negotiations will be prevailing market conditions, our financial information, market valuations of other companies that we and the underwriters believe to be comparable to us, estimates of our business potential, the present state of our development and other factors deemed relevant.

We offer no assurances that the initial public offering price will correspond to the price at which the common stock will trade in the public market subsequent to the offering or that an active trading market for the common stock will develop and continue after the offering.

Listing

We have applied to have our common stock listed on the Nasdaq Global Market under the trading symbol "VTYX."

Option to Purchase Additional Shares

We have granted to the underwriters an option, exercisable for 30 days from the date of this prospectus, to purchase, from time to time, in whole or in part, up to an aggregate of shares from us at the public offering price set forth on the cover page of this prospectus, less underwriting discounts and commissions. If the underwriters exercise this option, each underwriter will be obligated, subject to specified conditions, to purchase a number of additional shares proportionate to that underwriter's initial purchase commitment as indicated in the table above. This option may be exercised only if the underwriters sell more shares than the total number set forth on the cover page of this prospectus.

No Sales of Similar Securities

We, our officers, directors and holders of all or substantially all our outstanding capital stock have agreed, subject to specified exceptions, not to directly or indirectly:

- sell, offer to sell or contract to sell any of our securities,
- effect any short sale, or establish or increase any "put equivalent position" (as defined in Rule 16a-1(h) under the Exchange Act) or liquidate or decrease any "call equivalent position" (as defined in Rule 16a-1(b) under the Exchange Act) of any of our securities,
- pledge, hypothecate or grant any security interest in any of our securities,
- in any other way transfer or dispose of our securities,

- enter into any swap, hedge or similar arrangement or agreement that transfers, in whole or in part, the economic risk of ownership of any of our securities, regardless of whether any such transaction is to be settled in securities, in cash or otherwise,
- announce the offering of any of our securities,
- submit or file, or make any demand for or exercise any right with respect to, any registration statement under the Securities Act in respect of any of our securities,
- effect a reverse stock split, recapitalization, share consolidation, reclassification or similar transaction affecting our outstanding common stock, or
- publicly announce an intention to do any of the foregoing for a period of 180 days after the date of this prospectus without the prior written consent of Jefferies LLC, Evercore Group L.L.C. and Piper Sandler & Co..

This restriction terminates after the close of trading of the common stock on and including the 180th day after the date of this prospectus.

Jefferies LLC, Evercore Group L.L.C. and Piper Sandler & Co. may, in their sole discretion and at any time or from time to time before the termination of the 180-day period, release all or any portion of the securities subject to lock-up agreements. There are no existing agreements between the underwriters and any of our shareholders who will execute a lock-up agreement, providing consent to the sale of shares prior to the expiration of the lock-up period.

Stabilization

The underwriters have advised us that they, pursuant to Regulation M under the Exchange Act, certain persons participating in the offering may engage in short sale transactions, stabilizing transactions, syndicate covering transactions or the imposition of penalty bids in connection with this offering. These activities may have the effect of stabilizing or maintaining the market price of the common stock at a level above that which might otherwise prevail in the open market. Establishing short sales positions may involve either “covered” short sales or “naked” short sales.

“Covered” short sales are sales made in an amount not greater than the underwriters’ option to purchase additional shares of our common stock in this offering. The underwriters may close out any covered short position by either exercising their option to purchase additional shares of our common stock or purchasing shares of our common stock in the open market. In determining the source of shares to close out the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the option to purchase additional shares.

“Naked” short sales are sales in excess of the option to purchase additional shares of our common stock. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the shares of our common stock in the open market after pricing that could adversely affect investors who purchase in this offering.

A stabilizing bid is a bid for the purchase of shares of common stock on behalf of the underwriters for the purpose of fixing or maintaining the price of the common stock. A syndicate covering transaction is the bid for or the purchase of shares of common stock on behalf of the underwriters to reduce a short position incurred by the underwriters in connection with the offering. Similar to other purchase transactions, the underwriter’s purchases to cover the syndicate short sales may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our common stock. As a result, the price of our common stock may be higher than the price that might otherwise exist in the open market. A penalty bid is an arrangement permitting the underwriters to reclaim the selling concession otherwise accruing to a syndicate member in connection with the offering if the common stock originally sold by such syndicate member are purchased in a syndicate covering transaction and therefore have not been effectively placed by such syndicate member.

Neither we, nor any of the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our common stock. The underwriters are not obligated to engage in these activities and, if commenced, any of the activities may be discontinued at any time.

The underwriters may also engage in passive market making transactions in our common stock on the Nasdaq Global Market in accordance with Rule 103 of Regulation M during a period before the commencement of offers or sales of shares of our common stock in this offering and extending through the completion of distribution. A passive market maker must display its bid at a price not in excess of the highest independent bid of that security. However, if all independent bids are lowered below the passive market maker's bid, that bid must then be lowered when specified purchase limits are exceeded.

Electronic Distribution

A prospectus in electronic format may be made available by e-mail or on the web sites or through online services maintained by one or more of the underwriters or their affiliates. In those cases, prospective investors may view offering terms online and may be allowed to place orders online. The underwriters may agree with us to allocate a specific number of shares of common stock for sale to online brokerage account holders. Any such allocation for online distributions will be made by the underwriters on the same basis as other allocations. Other than the prospectus in electronic format, the information on the underwriters' web sites and any information contained in any other web site maintained by any of the underwriters is not part of this prospectus, has not been approved and/or endorsed by us or the underwriters and should not be relied upon by investors.

Other Activities and Relationships

The underwriters and certain of their affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging, financing and brokerage activities. The underwriters and certain of their affiliates have, from time to time, performed, and may in the future perform, various commercial and investment banking and financial advisory services for us and our affiliates, for which they received or will receive customary fees and expenses.

In the ordinary course of their various business activities, the underwriters and certain of their affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers, and such investment and securities activities may involve securities and/or instruments issued by us and our affiliates. If the underwriters or their respective affiliates have a lending relationship with us, they routinely hedge their credit exposure to us consistent with their customary risk management policies. The underwriters and their respective affiliates may hedge such exposure by entering into transactions which consist of either the purchase of credit default swaps or the creation of short positions in our securities or the securities of our affiliates, including potentially the common stock offered hereby. Any such short positions could adversely affect future trading prices of the common stock offered hereby. The underwriters and certain of their respective affiliates may also communicate independent investment recommendations, market color or trading ideas and/or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

Disclaimers About Non-U.S. Jurisdictions

European Economic Area

In relation to each Member State of the European Economic Area (each a Relevant State), no shares have been offered or will be offered pursuant to the offering to the public in that Relevant State prior to the publication of a prospectus in relation to the shares which has been approved by the competent authority in that Relevant State or, where appropriate, approved in another Relevant State and notified to the competent authority in that Relevant State, all in accordance with the Prospectus Regulation, except that the shares may be offered to the public in that Relevant State at any time:

(a) to any legal entity which is a qualified investor as defined under Article 2 of the Prospectus Regulation;
(b) to fewer than 150 natural or legal persons (other than qualified investors as defined under Article 2 of the Prospectus Regulation), subject to obtaining the prior consent of representatives for any such offer; or
(c) in any other circumstances falling within Article 1(4) of the Prospectus Regulation,

provided that no such offer of the shares shall require us or any of the representatives to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation.

For the purposes of this provision, the expression an "offer to the public" in relation to the shares in any Relevant State means the communication in any form and by any means of sufficient information on the terms of the offer and any shares to be offered so as to enable an investor to decide to purchase or subscribe for any shares, and the expression "Prospectus Regulation" means Regulation (EU) 2017/1129.

United Kingdom

No shares have been offered or will be offered pursuant to the offering to the public in the United Kingdom prior to the publication of a prospectus in relation to the Shares which has been approved by the Financial Conduct Authority, except that the shares may be offered to the public in the United Kingdom at any time:

(a) to any legal entity which is a qualified investor as defined under Article 2 of the UK Prospectus Regulation;
(b) to fewer than 150 natural or legal persons (other than qualified investors as defined under Article 2 of the UK Prospectus Regulation), subject to obtaining the prior consent of the representatives for any such offer; or
(c) in any other circumstances falling within Section 86 of the FSMA.

provided that no such offer of the shares shall require the Issuer or any Manager to publish a prospectus pursuant to Section 85 of the FSMA or supplement a prospectus pursuant to Article 23 of the UK Prospectus Regulation. For the purposes of this provision, the expression an "offer to the public" in relation to the shares in the United Kingdom means the communication in any form and by any means of sufficient information on the terms of the offer and any shares to be offered so as to enable an investor to decide to purchase or subscribe for any shares and the expression "UK Prospectus Regulation" means Regulation (EU) 2017/1129 as it forms part of domestic law by virtue of the European Union (Withdrawal) Act 2018.

Canada

(A) *Resale Restrictions*

The distribution of shares of common stock in Canada is being made only in the provinces of Ontario, Quebec, Alberta, British Columbia, Manitoba, New Brunswick and Nova Scotia on a private placement basis exempt from the requirement that we prepare and file a prospectus with the securities regulatory authorities in each province where trades of these securities are made. Any resale of the shares of our common stock in Canada must be made under applicable securities laws which may vary depending on the relevant jurisdiction, and which may require resales to be made under available statutory exemptions or under a discretionary exemption granted by the applicable Canadian securities regulatory authority. Purchasers are advised to seek legal advice prior to any resale of the shares of common stock.

(B) *Representations of Canadian Purchasers*

By purchasing shares of our common stock in Canada and accepting delivery of a purchase confirmation, a purchaser is representing to us and the dealer from whom the purchase confirmation is received that:

- the purchaser is entitled under applicable provincial securities laws to purchase the shares of our common stock without the benefit of a prospectus qualified under those securities laws as it is an "accredited investor" as defined under National Instrument 45-106 – Prospectus Exemptions or Section 73.3(1) of the Securities Act (Ontario), as applicable,
- the purchaser is a "permitted client" as defined in National Instrument 31-103 - Registration Requirements, Exemptions and Ongoing Registrant Obligations,
- where required by law, the purchaser is purchasing as principal and not as agent, and
- the purchaser has reviewed the text above under Resale Restrictions.

(C) *Conflicts of Interest*

Canadian purchasers are hereby notified that certain of the underwriters are relying on the exemption set out in section 3A.3 or 3A.4, if applicable, of National Instrument 33-105 – Underwriting Conflicts from having to provide certain conflict of interest disclosure in this document.

(D) *Statutory Rights of Action*

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if the prospectus (including any amendment thereto) such as this document contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser of these securities in Canada should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

(E) *Enforcement of Legal Rights*

All of our directors and officers as well as the experts named herein may be located outside of Canada and, as a result, it may not be possible for Canadian purchasers to effect service of process within Canada upon us or those persons. All or a substantial portion of our assets and the assets of those persons may be located outside of Canada and, as a result, it may not be possible to satisfy a judgment against us or those persons in Canada or to enforce a judgment obtained in Canadian courts against us or those persons outside of Canada.

(F) *Taxation and Eligibility for Investment*

Canadian purchasers of shares of common stock should consult their own legal and tax advisors with respect to the tax consequences of an investment in the shares of our common stock in their particular circumstances and about the eligibility of the shares of our common stock for investment by the purchaser under relevant Canadian legislation.

Australia

This prospectus is not a disclosure document for the purposes of Australia's Corporations Act 2001 (Cth) of Australia, or Corporations Act, has not been lodged with the Australian Securities & Investments Commission and is only directed to the categories of exempt persons set out below. Accordingly, if you receive this prospectus in Australia:

You confirm and warrant that you are either:

- a "sophisticated investor" under section 708(8)(a) or (b) of the Corporations Act;
- a "sophisticated investor" under section 708(8)(c) or (d) of the Corporations Act and that you have provided an accountant's certificate to the Company which complies with the requirements of section 708(8)(c)(i) or (ii) of the Corporations Act and related regulations before the offer has been made;
- a person associated with the Company under Section 708(12) of the Corporations Act; or
- a "professional investor" within the meaning of section 708(11)(a) or (b) of the Corporations Act.

To the extent that you are unable to confirm or warrant that you are an exempt sophisticated investor, associated person or professional investor under the Corporations Act any offer made to you under this prospectus is void and incapable of acceptance.

You warrant and agree that you will not offer any of the securities issued to you pursuant to this prospectus for resale in Australia within 12 months of those securities being issued unless any such resale offer is exempt from the requirement to issue a disclosure document under section 708 of the Corporations Act.

Hong Kong

No shares of our common stock have been offered or sold, and no shares of our common stock may be offered or sold, in Hong Kong, by means of any document, other than to persons whose ordinary business is to buy or sell shares or debentures, whether as principal or agent; or to "professional investors" as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong, or the SFO, and any rules made under that Ordinance; or in other circumstances which do not result in the document being a "prospectus" as defined in the Companies Ordinance (Cap. 32) of Hong Kong, or the CO, or which do not constitute an offer or invitation to the public for the purpose of the CO or the SFO. No document, invitation or advertisement relating to the shares of our common stock has been issued or may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted under the securities laws of Hong Kong) other than with respect to shares of our common stock which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" as defined in the SFO and any rules made under that Ordinance.

This prospectus has not been registered with the Registrar of Companies in Hong Kong. Accordingly, this prospectus may not be issued, circulated or distributed in Hong Kong, and the shares of our common stock

may not be offered for subscription to members of the public in Hong Kong. Each person acquiring the shares of our common stock will be required, and is deemed by the acquisition of the shares of our common stock, to confirm that he is aware of the restriction on offers of the shares of our common stock described in this prospectus and the relevant offering documents and that he is not acquiring, and has not been offered any shares of our common stock in circumstances that contravene any such restrictions.

Israel

This document does not constitute a prospectus under the Israeli Securities Law, 5728-1968, or the Securities Law, and has not been filed with or approved by the Israel Securities Authority. In Israel, this prospectus is being distributed only to, and is directed only at, and any offer of shares is directed only at, (i) a limited number of persons in accordance with the Israeli Securities Law and (ii) investors listed in the first addendum, or the Addendum, to the Israeli Securities Law, consisting primarily of joint investment in trust funds, provident funds, insurance companies, banks, portfolio managers, investment advisors, members of the Tel Aviv Stock Exchange, underwriters, venture capital funds, entities with equity in excess of NIS 50 million and "qualified individuals," each as defined in the Addendum (as it may be amended from time to time), collectively referred to as qualified investors (in each case, purchasing for their own account or, where permitted under the Addendum, for the accounts of their clients who are investors listed in the Addendum). Qualified investors are required to submit written confirmation that they fall within the scope of the Addendum, are aware of the meaning of same and agree to it.

Japan

The offering has not been and will not be registered under the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948 of Japan, as amended), or FIEL, and the underwriters will not offer or sell any securities, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan (which term as used herein means any person resident in Japan, including any corporation or other entity organized under the laws of Japan), or to others for re-offering or resale, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan, except pursuant to an exemption from the registration requirements of, and otherwise in compliance with, the FIEL and any other applicable laws, regulations and ministerial guidelines of Japan.

Singapore

This prospectus has not been and will not be lodged or registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the common stock may not be circulated or distributed, nor may the common stock be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore, or the SFA, (ii) to a relevant person pursuant to Section 275(1), or any person pursuant to Section 275(1A), and in accordance with the conditions specified in Section 275, of the SFA, or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the shares of our common stock are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

- a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or
- a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor, securities (as defined in Section 239(1) of the SFA) of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the shares of our common stock pursuant to an offer made under Section 275 of the SFA except:
- to an institutional investor or to a relevant person defined in Section 275(2) of the SFA, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA;
- where no consideration is or will be given for the transfer;
- where the transfer is by operation of law;
- as specified in Section 276(7) of the SFA; or
- as specified in Regulation 32 of the Securities and Futures (Offers of Investments) (Shares and Debentures) Regulations 2005 of Singapore.

Switzerland

The shares may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange, or the SIX, or on any other stock exchange or regulated trading facility in Switzerland. This prospectus has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this prospectus nor any other offering or marketing material relating to the securities or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this prospectus nor any other offering or marketing material relating to the offering, us or the securities have been or will be filed with or approved by any Swiss regulatory authority. In particular, this prospectus will not be filed with, and the offer of securities will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA, and the offer of securities has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes, or the CISA. The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of securities.

LEGAL MATTERS

The validity of the shares of the common stock offered in this prospectus will be passed upon for us by Wilson Sonsini Goodrich & Rosati, Professional Corporation, San Diego, California. Cooley LLP, San Diego, California, is acting as counsel for the underwriters.

EXPERTS

The financial statements included in this Prospectus have been audited by Ernst & Young LLP, an independent registered public accounting firm, as stated in their report included herein. Such financial statements have been so included in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the shares of our common stock offered by this prospectus. This prospectus constitutes only a part of the registration statement. Some items are contained in exhibits to the registration statement as permitted by the rules and regulations of the SEC. For further information with respect to us and our common stock, we refer you to the registration statement, including the exhibits. Statements contained in this prospectus concerning the contents of any contract, agreement or other document are not necessarily complete and you should refer to the exhibits attached to the registration statement for copies of the actual contract, agreement or other document. Each statement in this prospectus relating to a contract or document filed as an exhibit is qualified in all respects by the filed exhibit. The SEC maintains an Internet website that contains reports, proxy statements and other information about issuers, like us, that file electronically with the SEC. The address of that website is www.sec.gov.

When we complete this offering, we will become subject to the information and reporting requirements of the Exchange Act and, in accordance with this law, will file periodic reports, proxy statements and other information with the SEC. These periodic reports, proxy statements and other information will be available for inspection and copying at the SEC's public reference facilities and the website of the SEC referred to above. We also maintain a website at www.ventyxbio.com, at which you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. The information contained on our website is not a part of this prospectus and the inclusion of our website address in this prospectus is an inactive textual reference only.

VENTYX BIOSCIENCES, INC.
CONSOLIDATED FINANCIAL STATEMENTS
Years ended December 31, 2019 and 2020 and Six Months ended June 30, 2020 and 2021

OPPILAN PHARMA, LTD.

CONSOLIDATED FINANCIAL STATEMENTS
Years ended May 31, 2019 and 2020

Six-Month Periods Ended November 30, 2019 and 2020 (unaudited)
Contents

ZOMAGEN BIOSCIENCES, LTD.
CONSOLIDATED FINANCIAL STATEMENTS
Years ended December 31, 2019 and 2020

UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL INFORMATION

VENTYX BIOSCIENCES, INC.

Consolidated Financial Statements

For the Years Ended December 31, 2019, 2020 and Six Months Ended June 30, 2020, 2021

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and the Board of Directors of
Ventyx Biosciences, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Ventyx Biosciences, Inc. (the Company) as of December 31, 2019 and 2020, the related statements of operations and comprehensive loss, convertible preferred stock and stockholders' deficit and cash flows for the years then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2019 and 2020, and the results of its operations and its cash flows for the years then ended in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB and in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financing reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2021.

San Diego, California
August 20, 2021

Ventyx Biosciences, Inc.
Consolidated Balance Sheets
(in thousands, except share and par value amounts)

	DECEMBER 31,		JUNE 30,
	2019	2020	2021
			(UNAUDITED)
Assets			
Current assets:			
Cash and cash equivalents	$ 309	$ 244	$ 102,788
Prepaid expenses (includes related party amounts of $0, $0 and $17, respectively)	40	1	2,240
Total current assets	349	245	105,028
Property and equipment, net	—	—	72
Other long-term assets	—	—	816
Total assets	$ 349	$ 245	$ 105,916
Liabilities and stockholders' equity			
Current liabilities			
Accounts payable (includes related party amounts of $70, $238 and $0, respectively)	$ 362	$ 1,102	$ 2,373
Accrued expenses (includes related party amounts of $3, $17 and $365, respectively)	269	301	5,691
Total current liabilities	631	1,403	8,064
Change of control derivative liability - related party	—	16,849	—
Convertible promissory notes - related party	3,846	2,920	—
Convertible SAFE notes at fair value - related party	—	9,727	—
Total liabilities	4,477	30,899	8,064
Commitments and contingencies			
Convertible preferred stock:			
Series A convertible preferred shares, $0.0001 par value; 0, 0 and 120,000,000 shares authorized at December 31, 2019, 2020 and June 30, 2021, respectively; 0, 0 and 119,879,441 issued and outstanding at December 31, 2019, 2020 and June 30, 2021 (unaudited), respectively; liquidation preference of $114,300 at June 30, 2021 (unaudited)	—	—	116,279
Series A-1 convertible preferred shares, $0.0001 par value; 0, 0 and 180,000,000 shares authorized at December 31, 2019, 2020 and June 30, 2021, respectively; 0, 0 and 179,490,370 shares issued and outstanding at December 31, 2019, 2020 and June 30, 2021 (unaudited), respectively	—	—	57,437
Stockholders' deficit:			
Common stock, $0.0001 par value; 47,603,832, 47,603,832 and 365,000,000 shares authorized at December 31, 2019, 2020 and June 30, 2021 (unaudited), respectively; 20,805,120, 20,920,824 and 39,484,525 shares issued at December 31, 2019, 2020 and June 30, 2021 (unaudited), respectively; 18,427,408, 19,696,293 and 37,838,357 shares outstanding at December 31, 2019, 2020 and June 30, 2021 (unaudited), respectively.	—	—	4
Additional paid-in capital	199	1,847	11,401
Accumulated other comprehensive loss	—	—	(12)
Accumulated deficit	(4,327)	(32,501)	(87,257)
Total stockholders' deficit	(4,128)	(30,654)	(75,864)
Total liabilities, convertible preferred stock and stockholders' deficit	$ 349	$ 245	$ 105,916

See accompanying notes.

Ventyx Biosciences, Inc.
Consolidated Statements of operations
(in thousands, except share and per share data)

	YEARS ENDED DECEMBER 31,		SIX MONTHS ENDED JUNE 30,	
	2019	2020	2020	2021
			(UNAUDITED)	
Operating expenses:				
Research and development (includes related party amounts of $1,374, $965, $647 and $462, respectively)	$ 3,552	$ 6,366	$ 3,069	$ 34,112
General and administrative (includes related party amounts of $296, $400, $221 and $116, respectively)	628	684	305	2,422
Total operating expenses	4,180	7,050	3,374	36,534
Loss from operations	(4,180)	(7,050)	(3,374)	(36,534)
Other expense:				
Other expense	1	1	—	44
Interest expense - related party	146	358	111	99
Change in fair value of notes and derivative - related party	—	20,765	831	11,051
Change in fair value of Series A tranche liability	—	—	—	5,476
Total other expense	147	21,124	942	16,670
Net loss	(4,327)	(28,174)	(4,316)	(53,204)
Deemed dividend	—	—	—	(1,552)
Net loss attributable to common stockholders	$ (4,327)	$ (28,174)	$ (4,316)	$ (54,756)
Net loss	$ (4,327)	$ (28,174)	$ (4,316)	$ (53,204)
Foreign currency translation	—	—	—	(12)
Comprehensive loss	$ (4,327)	$ (28,174)	$ (4,316)	$ (53,216)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.27)	$ (1.48)	$ (0.23)	$ (1.85)
Shares used to compute basic and diluted net loss per share	15,897,424	19,022,848	18,721,146	29,607,406

See accompanying notes.

Ventyx Biosciences, Inc.
Consolidated Statements of Convertible Preferred Stock and Stockholder's Deficit
(in thousands, except share data)

	SERIES A CONVERTIBLE PREFERRED STOCK		SERIES A-1 CONVERTIBLE PREFERRED STOCK		COMMON STOCK		ADDITIONAL PAID-IN	ACCUMULATED OTHER COMPREHENSIVE	ACCUMULATED	TOTAL STOCKHOLDER'S
	SHARE	AMOUNT	SHARE	AMOUNT	SHARE	AMOUNT	CAPITAL	LOSS	DEFICIT	DEFICIT
Balance at December 31, 2018	—	$ —	—	$ —	1,587	$ —	$ —	$ —	$ —	$ —
Vesting of restricted common stock	—	—	—	—	18,348,687	—	—	—	—	—
Issuance of common stock upon exercise of stock options	—	—	—	—	77,134	—	1	—	—	1
Stock-based compensation expense	—	—	—	—	—	—	198	—	—	198
Net loss	—	—	—	—	—	—	—	—	(4,327)	(4,327)
Balance at December 31, 2019	—	$ —	—	$ —	18,427,408	$ —	$ 199	$ —	$ (4,327)	$ (4,128)
Modification of debt instruments with related party	—	—	—	—	—	—	1,601	—	—	1,601
Vesting of restricted common stock	—	—	—	—	1,037,477	—	—	—	—	—
Issuance of common stock upon exercise of stock options	—	—	—	—	231,408	—	2	—	—	2
Stock-based compensation expense	—	—	—	—	—	—	45	—	—	45
Net loss	—	—	—	—	—	—	—	—	(28,174)	(28,174)
Balance at December 31, 2020	—	$ —	—	$ —	19,696,293	$ —	$ 1,847	$ —	$ (32,501)	$ (30,654)
Issuance of preferred stock upon modification and conversion of notes (unaudited)	—	—	121,597,908	38,911	—	—	1,735	—	—	1,735
Acquisition of Oppilan and Zomagen (unaudited)	—	—	57,892,462	18,526	7,831,449	1	2,818	—	—	2,819
Issuance of preferred stock and common stock, net of legal fees (unaudited)	119,879,441	112,307	—	—	4,850,428	1	1,552	—	(1,552)	1
Conversion of tranche liability to Series A preferred stock and common stock (unaudited)	—	3,972	—	—	4,850,428	1	3,056	—	—	3,057
Vesting of restricted common stock (unaudited)	—	—	—	—	489,812	1	—	—	—	1
Issuance of common stock upon exercise of stock options (unaudited)	—	—	—	—	119,947	—	25	—	—	25
Stock-based compensation	—	—	—	—	—	—	368	—	—	368

expense (unaudited)										
Foreign currency translation (unaudited)	—	—	—	—	—	—	—	(12)	—	(12)
Net loss (unaudited)	—	—	—	—	—	—	—	—	(53,204)	(53,204)
Balance at June 30, 2021 (unaudited)	119,879,441	$ 116,279	179,490,370	$ 57,437	37,838,357	$ 4	$ 11,401	$ (12)	$ (87,257)	$ (75,864)

Ventyx Biosciences, Inc.
Consolidated Statements of Cash Flows
(in thousands)

	YEARS ENDED DECEMBER 31,		SIX MONTHS ENDED JUNE 30,	
	2019	2020	2020	2021
			(UNAUDITED)	
Operating activities				
Net loss	$ (4,327)	$ (28,174)	$ (4,316)	$ (53,204)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation	—	—	—	5
Stock-based compensation	198	45	17	368
Effect of exchange rates on cash	—	—	—	(12)
Non-cash interest - related party	146	358	111	99
Exchange of notes for acquired intellectual property - related party	750	—	—	—
Change in fair value of related party notes	—	20,764	831	11,051
Change in fair value of Series A tranche liability	—	—	—	5,476
Acquired in-process research and development	—	—	—	21,781
Changes in operating assets and liabilities				
Prepaid expenses (includes related party amounts of $0, $0, $0 and ($17), respectively)	(39)	39	(453)	(1,737)
Accounts payable (includes related party amounts of $70, $169, $153 and ($421), respectively)	361	591	424	171
Accrued expenses (includes related party amounts amounts of $3, $14, $17 and $265, respectively)	269	182	961	3,068
Net cash used in operating activities	(2,642)	(6,195)	(2,425)	(12,934)
Investing activities				
Acquisition of Oppilan and Zomagen, net of cash	—	—	—	1,899
Purchases of property and equipment	—	—	—	(11)
Net cash provided by investing activities	—	—	—	1,888
Financing activities				
Proceeds from issuance of convertible preferred stock, net of offering costs	—	—	—	113,415
Deferred offering costs	—	—	—	(300)
Proceeds from exercise of stock options	1	2	—	25
Proceeds from issuance of SAFE Notes, net	—	6,128	2,150	450
Proceeds from issuance of Convertible Notes, net	2,950	—	—	—
Net cash provided by financing activities	2,951	6,130	2,150	113,590
Increase (decrease) in cash and cash equivalents	$ 309	$ (65)	$ (275)	$ 102,544
Cash and cash equivalents, beginning of period	$ —	$ 309	$ 309	$ 244
Cash and cash equivalents, end of period	$ 309	$ 244	$ 34	$ 102,788
Supplemental disclosure for non-cash activities				
Exchange of convertible promissory notes for intellectual property-related party	$ 750	$ —	$ —	$ —
Amendment to convertible promissory notes - related party	$ —	$ 2,706	$ —	$ —
Conversion of promissory and SAFE notes - related party	$ —	$ —	$ —	$ 38,911
Stock issued for the acquisition of Oppilan and Zomagen	$ —	$ —	$ —	$ 21,345
Unpaid deferred offering costs	$ —	$ —	$ —	$ 453
Vesting of restricted stock	$ —	$ —	$ —	$ 1
Taxes paid	$ —	$ 1	$ —	$ 1

1. Organization and Business

Organization

Ventyx Biosciences, Inc. ("Ventyx" or "the Company") is a pre-clinical and clinical-stage pharmaceutical company focused on immunology across diverse therapeutic areas, incorporated in the State of Delaware in November 2018, with its principal operations in California. The Company leverages its drug discovery and development expertise to develop novel and differentiated therapeutics that target both the innate and adaptive immune system.

On February 7, 2019, the Company acquired all rights, title and interests related to compounds that inhibit tyrosine kinase2 (TYK2), from Vimalan Biosciences, Inc., a related party (Note 11).

On February 26, 2021, the Company closed a Series A and Series A-1 Preferred Stock financing for initial gross proceeds of $57.3 million. In connection with the financing the company acquired the outstanding equity of Oppilan Pharma, Ltd ("Oppilan") and Zomagen Biosciences ("Zomagen"). The financial statements reflect the consolidation of Ventyx Biosciences, Inc. along with its wholly owned subsidiaries Oppilan and Zomagen, as of and for the four months ended June 30, 2021 (Note 5).

Liquidity and Capital Resources

The Company has experienced net losses since inception and, as of June 30, 2021 had an accumulated deficit of $87.3 million. From incorporation in November 2018 through June 30, 2021, the Company has devoted substantially all of its resources to organizing and staffing the company, business planning, raising capital, developing and optimizing its technology platform, identifying potential product candidates, undertaking research and preclinical studies, and providing general and administrative support for these operations. Substantially all the Company's operations have been funded by the issuances of convertible promissory notes ("Convertible Notes") and Simple Agreements for Future Equity ("SAFEs" or "Convertible SAFE Notes") and convertible preferred stock.

At June 30, 2021, the Company had cash and cash equivalents of $102.8 million, which includes proceeds received from the Company's first and second tranche closings of Series A and Series A-1 Preferred Stock of $57.3 million and $57.0 million at February 26, 2021 and June 10, 2021, respectively (Note 7). Based on the Company's current business plan, management believes that existing cash and cash equivalents will be sufficient to fund the Company's obligations for twelve months from the issuance of these financial statements. The accompanying financial statements have been prepared assuming the Company will continue as a going concern, which contemplates the realization of assets and settlement of liabilities in the normal course of business. The financial statements do not include any adjustments for the recovery and classification of assets or the amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

In addition to the foregoing, the Company is closely monitoring the impact of the COVID-19 pandemic on its business and has taken steps designed to protect the health and safety of its employees while continuing its operations. Given the level of uncertainty regarding the duration and impact of the COVID-19 pandemic on capital markets and the United States economy, the Company is currently unable to assess the impact of the COVID-19 pandemic on its future access to capital. The Company is continuing to monitor the spread of COVID-19 and its potential impact on the Company's operations. The full extent to which the COVID-19 pandemic will impact the Company's business, results of operations, financial condition, clinical trials, and preclinical research will depend on future developments that are highly uncertain, including actions taken to contain or treat COVID-19 and their effectiveness, as well as the economic impact on national and international markets.

2. Summary of Significant Accounting Policies

Basis of Presentation

The presentation of the Company's financial statements for years ended December 31, 2019 and 2020 reflect the financial results of Ventyx Biosciences as a standalone business. The presentation of the Company's financial statements for the six months ended June 30, 2021, reflect the financial results of Ventyx Biosciences, Inc and its two acquired subsidiaries, Zomagen Biosciences and Oppilan Pharma, Ltd. on a consolidated basis, as of the acquisition date February 26, 2021 (Note 5).

Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. generally accepted accounting principles (GAAP), requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. On an ongoing basis, the Company evaluates its estimates and judgments, which are based on historical and anticipated results and trends and on various other assumptions that management believes to be reasonable under the circumstances. By their nature, estimates are subject to an inherent degree of uncertainty and, as such, actual results may differ from management's estimates.

Unaudited Consolidated Interim Financial Information

The accompanying consolidated interim balance sheet as of June 30, 2021, the statements of operations and comprehensive loss, and the statements of cash flows for the six months ended June 30, 2020 and 2021 and the statements of convertible preferred stock and stockholders' deficit for the six months ended June 30, 2021 and the related footnote disclosures are unaudited. In management's opinion, the unaudited consolidated interim financial statements have been prepared on the same basis as the audited financial statements and include all adjustments, which include only normal recurring adjustments, necessary for the fair presentation of the Company's financial position as of June 30, 2021 and its results of operations and cash flows for the six months ended June 30, 2020 and 2021 in accordance with GAAP. The results for the six months ended June 30, 2021 are not necessarily indicative of the results expected for the full fiscal year or any other interim period.

Segments

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker, the Chief Executive Officer, in making decisions regarding resource allocation and assessing performance. The Company views its operations and manages its business as one operating segment.

Cash and Cash Equivalents

Cash and cash equivalents consist of checking, money market and highly liquid investments that are readily convertible to cash and that have an original maturity of three months or less from date of purchase. The carrying amounts approximate fair value due to the short maturities of these instruments.

Property and Equipment

The Company records property and equipment at cost, which consists of laboratory equipment, furniture and fixtures, and computer hardware and software. Property and equipment is depreciated using the straight-line method over the estimated useful lives (generally three to seven years).

Concentrations of Credit Risk

The Company's financial instruments that are exposed to concentrations of credit risk consist primarily of cash and cash equivalents. The Company maintains deposits in government insured financial institutions in excess of government insured limits. The Company invests its cash balances in financial institutions that it believes have high credit quality, has not experienced any losses on such accounts and does not believe it is exposed to significant credit risk.

Deferred Offering Costs

The Company has deferred offering costs consisting of accounting and legal fees directly attributable to the preparation of the Company's draft registration statement. The deferred offering costs will be offset against the proceeds received upon the completion of the planned offering. In the event the planned IPO is terminated, all the deferred offering costs will be expensed within the Company's statements of operations and comprehensive loss. As of June 30, 2021, $753,008 of deferred offering costs were recorded within long term assets on the balance sheet. No such costs were included on the balance sheets as of December 31, 2019 and 2020, respectively.

Fair Value of Financial Instruments

The Company follows Accounting Standards Codification ("ASC") ASC 820-10, *Fair Value Measurements and Disclosures*, ("ASC 820-10") issued by the FASB with respect to fair value reporting for financial assets and liabilities. The guidance defines fair value, provides guidance for measuring fair value and requires certain disclosures. The guidance does not apply to measurements related to share-based payments. The guidance discusses valuation techniques such as the market approach (comparable market prices), the income approach (present value of future income or cash flow), and the cost approach (cost to replace the service capacity of an asset or replacement cost). The guidance establishes a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value into three broad levels.

The Company's financial instruments include cash and cash equivalents, prepaid expenses and other assets, accounts payable, accrued expenses, Convertible Notes and related Change of Control Derivative Liability, Convertible SAFE Notes and Series A Tranche Liability. Fair value estimates of these instruments are made at a specific point in time, based on relevant market information. These estimates may be subjective in nature and involve uncertainties and matters of significant judgement and therefore cannot be determined with precision. The carrying amount of cash and cash equivalents, prepaid expenses and other assets, accounts payable and accrued expenses are generally considered to be representative of their respective values because of the short-term nature of those instruments. The Company believes that the fair value of its Convertible Notes approximates its carrying value.

Derivative Financial Instruments

The Company does not use derivative instruments to hedge exposures to cash flow, market, or foreign currency risks. The Company evaluates all of its financial instruments, to determine if such instruments are derivatives or contain features that qualify as embedded derivatives. The Company values its derivatives using a combination of probability analysis and Monte Carlo simulation or other acceptable valuation models. Derivative instruments are valued at inception and subsequent valuation dates. The classification of derivative instruments, including whether such instruments should be recorded as liabilities, is re-assessed at the end of each reporting period.

Research and Development Expenses

The Company's research and development costs consist primarily of salaries, payroll taxes, employee benefits, and stock-based compensation charges for those individuals involved in ongoing research and development efforts; as well as fees paid to consultants, third party research organizations, laboratory supplies, and development compound materials. All research and development costs are charged to expense as incurred.

Clinical Trial Expenses

The Company makes payments in connection with its clinical trials under contracts with contract research organizations that support conducting and managing clinical trials. The financial terms of these agreements are subject to negotiation and vary from contract to contract and may result in uneven payment flows. Generally, these agreements set forth the scope of work to be performed at a fixed fee, unit price or on a time and materials basis. A portion of the Company's obligation to make payments under these contracts depends on factors such as the successful enrollment or treatment of patients or the completion of other clinical trial milestones.

Expenses related to clinical trials are accrued based on estimates and/or representations from service providers regarding work performed, including actual level of patient enrollment, completion of patient studies and progress of the clinical trials. Other incidental costs related to patient enrollment or treatment are accrued when reasonably certain. If the amounts the Company is obligated to pay under clinical trial agreements are modified (for instance, as a result of changes in the clinical trial protocol or scope of work to be performed), the Company adjusts the accruals accordingly. Revisions to the contractual payment obligations are charged to expense in the period in which the facts that give rise to the revision become reasonably certain.

Patent Costs

Costs related to filing and pursuing patent applications are expensed as incurred, as recoverability of such expenditures is uncertain. These costs are included in general and administrative expenses within the Company's statements of operations and comprehensive loss.

Debt Issuance Costs

Debt issuance costs incurred to obtain debt financing are deferred and are amortized over the term of the debt using the effective interest method. The costs are recorded as a reduction to the carrying value of the debt and are included in interest expense for the twelve months ended December 31, 2020 and the six months ended June 30, 2021.

Income Taxes

The Company follows the Financial Accounting Standards Board, or FASB, *Accounting Standards Codification*, or ASC, 740, *Income Taxes*, or ASC 740, in reporting deferred income taxes. ASC 740 requires a company to recognize deferred tax assets and liabilities for expected future income tax consequences of events that have been recognized in the Company's financial statements. Under this method, deferred tax assets and liabilities are determined based on temporary differences between financial statement carrying amounts and the tax basis of assets and liabilities using enacted tax rates in the years in which the temporary differences are expected to reverse. Valuation allowances are provided if, based on the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

The Company accounts for uncertain tax positions pursuant to ASC 740, which prescribes a recognition threshold and measurement process for financial statement recognition of uncertain tax positions taken or expected to be taken in a tax return. If the tax position meets this threshold, the benefit to be recognized is measured as the tax benefit having the highest likelihood of being realized upon ultimate settlement with the taxing authority. The Company recognizes interest accrued related to unrecognized tax benefits and penalties in the provision for income taxes.

Stock-Based Compensation

The Company accounts for stock-based compensation expense related to employee stock options and restricted stock by estimating the fair value on the date of grant. The Company estimates the fair value of these awards to employees and non-employees using the Black-Scholes option pricing model, which requires the input of highly subjective assumptions, including (a) the risk-free interest rate, (b) the expected volatility of the Company's stock, (c) the expected term of the award, and (d) the expected dividend yield. Due to the lack of an adequate history of a public market for the trading of the Company's common, the Company has based its estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded. For these analyses, the Company has selected companies with comparable characteristics, including enterprise value, risk profiles, and position within the industry, and with historical share price information sufficient to meet the expected life of the stock-based awards.

The Company has estimated the expected life of its employee stock options using the "simplified" method, whereby the expected life equals the average of the vesting term and the original contractual term of the option. The risk-free interest rates for periods within the expected life of the option are based on the yields of zero-coupon U.S. treasury securities. Under the fair value recognition provisions of the authoritative guidance for stock-based compensation awards, the Company measures the fair value of restricted stock and stock options

at the grant date, and the fair value is recognized as expense on a straight-line basis over the requisite service period or contractual term. Forfeitures are recognized as incurred.

Convertible Preferred Stock

The Company has issued shares of Series A and Series A-1 Convertible Preferred Stock that are conditionally redeemable, as the redemption rights are either within the control of the holder or subject to redemption upon the occurrence of uncertain events not solely within the Company's control, and as such, are classified as temporary equity.

Common Stock Split

On February 26, 2021, the Company effected a 1 for 7.933972 stock split of its common stock. The par value and the authorized shares of the common stock were not adjusted as a result of the stock split. The accompanying financial statements and notes to the financial statements give retroactive effect to the stock split for all periods presented.

Net Loss Per Share

Basic net loss per share of common stock is computed by dividing net loss attributable to common stockholders by the weighted average number of shares of common stock outstanding for the period. The following table sets forth the computation of basic and diluted net loss per share attributable to common shareholders:

	YEAR ENDED DECEMBER 31,		SIX MONTHS ENDED JUNE 30,	
	2020	2021	2020	2021
Numerator				
Net loss	$ (4,327)	$ (28,174)	$ (4,316)	$ (53,204)
Deemed dividend	—	—	—	(1,552)
Net loss attributable to common stockholders	$ (4,327)	$ (28,174)	$ (4,316)	$ (54,756)
Denominator				
Weighted average common shares	15,897,424	19,022,848	18,721,146	29,607,406
Basic and diluted net loss per share attributable to common stockholders	$ (0.27)	$ (1.48)	$ (0.23)	$ (1.85)

The table below provides potentially dilutive securities not included in the calculation of the diluted net loss per share (in common stock equivalent shares), because to do so would be anti-dilutive. Excluded from the table is the potential impact from convertible notes and SAFE agreements, as the number of shares is unknown:

	YEAR ENDED DECEMBER 31,		SIX MONTHS ENDED JUNE 30,	
	2019	2020	2020	2021
Shares issuable upon exercise of stock options	7,451,315	14,803,420	14,803,420	23,357,778
Shares issuable upon conversion of Series A and A-1 Preferred Stock	—	—	—	299,369,811
Total	7,451,315	14,803,420	14,803,420	322,727,589

Comprehensive Loss

Comprehensive loss is defined as a change in equity during a period from transactions and other events and circumstances from non-owner sources. The Company's only component of other comprehensive loss is loss

on foreign currency translation. Comprehensive losses have been reflected in the consolidated statements of operations and comprehensive loss and as a separate component of the consolidated statements of convertible preferred stock and stockholders' equity for all periods presented.

Acquisitions

The Company accounts for acquisitions of an asset or group of similar identifiable assets that do not meet the definition of a business as asset acquisition using the cost accumulation method, whereby the cost of the acquisition, including certain transaction costs, is allocated to the assets acquired on the basis of their relative fair values. No goodwill is recognized in an asset acquisition. Intangible assets acquired in an asset acquisition for use in research and development activities which have no alternative future use are expensed as in-process research and development on the acquisition date. Intangible assets acquired for use in research and development activities which have an alternative future use are capitalized as in-process research and development. Future costs to develop these assets are recorded to research and development expense as they are incurred.

Recently Issued Accounting Standards

Recently Issued Accounting Standards Not Yet Adopted

In February 2016, the FASB issued ASU No. 2016-02, *Leases* ("ASU 2016-02"). The new standard establishes a right-of-use model and requires a lessee to recognize on the balance sheet a right-of-use asset and corresponding lease liability for all leases with terms longer than 12 months. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. In June 2020, the FASB issued ASU No. 2020-05, *Revenue from Contracts with Customers (Topic 606) and Leases (Topic 842): Effective Dates for Certain Entities* ("ASU 2020-05"), which delays adoption of Topic 606 and Topic 842. Pursuant to the delayed adoption provided for under ASU 2020-05, the new leasing standard is effective for the Company's annual periods beginning after December 15, 2021 with early adoption permitted. The Company is currently evaluating the impact that the adoption of this guidance will have on its financial statements and related disclosures.

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments–Credit Losses: Measurement of Credit Losses on Financial Instruments* ("ASU 2016-13") which amends the impairment model by requiring entities to use a forward-looking approach based on expected losses to estimate credit losses on certain types of financial instruments, including trade receivables and available-for-sale debt securities. ASU 2016-13 is effective for the Company's annual periods beginning after 2023, with early adoption permitted. The Company is currently evaluating the impact the adoption of this guidance will have on its financial statements and related disclosures.

In August 2020, FASB issued ASU No. 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity* ("ASU 2020-06"), which, among other things, provides guidance on how to account for contracts on an entity's own equity. This ASU simplifies the accounting for certain financial instruments with characteristics of liabilities and equity. Specifically, the ASU eliminated the need for the Company to assess whether a contract on the entity's own equity (1) permits settlement in unregistered shares, (2) whether counterparty rights rank higher shareholder's rights, and (3) whether collateral is required. In addition, the ASU requires incremental disclosure related to contracts on the entity's own equity and clarifies the treatment of certain financial instruments accounted for under this ASU on earnings per share. This ASU may be applied on a full retrospective or modified retrospective basis. The amendments in the ASU are effective for the Company's fiscal years beginning after December 15, 2023, including interim periods within those fiscal years. Early adoption of the ASU is permitted for fiscal years beginning after December 15, 2020, including interim periods within those fiscal years. The Company is currently evaluating the potential impact that this standard may have on its financial statements and related disclosures.

Recently Adopted Accounting Standards

In July 2017, the FASB issued ASU No. 2017-11, *Earnings Per Share (Topic 260); Distinguishing Liabilities from Equity (Topic 480); Derivatives and Hedging (Topic 815): Accounting for Certain Financial Instruments with Down Round Features (*"ASU 2017-11"*)*. The amendments of this ASU update the classification analysis of certain equity-linked financial instruments, or embedded features, with down round features, as well as clarify existing disclosure requirements for equity-classified instruments. When determining whether certain financial instruments should be classified as liabilities or equity instruments, a down round feature no longer precludes equity classification when assessing whether the instrument is indexed to an entity's own stock. The accounting standard update is effective for fiscal years beginning after December 15, 2019. The Company adopted this standard in the first quarter of 2020 and evaluated all outstanding financial instruments that would fall under the scope of ASU 2017-11. The Company has evaluated the effect that the updated standard had on its internal processes, financial statements and related disclosures, and has determined that the adoption did not have a material impact on the Company's historical financial statements and has not recorded a cumulative-effect adjustment to the balance sheet.

In November 2018, the FASB issued ASU No. 2018-18 ("ASU 2018-18"), which clarifies the interaction between ASC Topic 808, *Collaborative Arrangements*, and ASC Topic 606, *Revenue from Contracts with Customers*. This guidance, among other items, clarifies that certain transactions between collaborative participants should be accounted for as revenue under Topic 606 when the collaborative arrangement participant is a customer in the context of a unit of account. ASU 2018-18 is effective for the Company's fiscal years beginning after December 15, 2020. The Company adopted this standard in the first quarter of 2021. The Company has evaluated the effect that the updated standard had on its internal processes, financial statements and related disclosures, and has determined that the adoption did not have a material impact on the Company's historical financial statements.

In December 2019, the FASB issued ASU No. 2019-12, *Simplifying the Accounting for Income Taxes* ("ASU 2019-12"), as part of its initiative to reduce complexity in accounting standards. The amendments in the ASU are effective for the Company's fiscal years beginning after December 15, 2020, including interim periods therein. The Company adopted this standard in the first quarter of 2021. The Company has evaluated the effect that the updated standard had on its internal processes, financial statements and related disclosures, and has determined that the adoption did not have a material impact on the Company's historical financial statements.

3. Fair Value Measurements

The Company follows ASC 820-10 which, among other things, defines fair value and requires the establishment of a framework for measuring fair value and disclosure about fair value measurements using a three-tier approach. These tiers include:

Level 1 - Quoted prices (unadjusted) in active markets for identical assets or liabilities;

Level 2 - Inputs other than quoted prices included within Level 1 that are either directly or indirectly observable;

Level 3 - Unobservable inputs in which little or no market activity exists, therefore requiring an entity to develop its own assumptions about the assumptions that market participants would use in pricing.

The carrying amounts of the Company's current financial assets and current financial liabilities are considered to be representative of their respective fair values because of the short-term nature of those instruments. Financial assets and liabilities that are measured at fair value on a recurring basis include cash equivalents, the change of control derivative liability and fair value of convertible SAFE notes. None of the Company's non-financial assets or liabilities are recorded at fair value on a non-recurring basis. The following table summarizes

the instruments that are measured at fair value on a recurring basis and are categorized using the fair value hierarchy (in thousands) as of December 31, 2020, and June 30, 2021:

	TOTAL FAIR VALUE	QUOTED PRICES FOR IDENTICAL ASSETS (LEVEL 1)	SIGNIFICANT OTHER OBSERVABLE INPUTS (LEVEL 2)	SIGNIFICANT UNOBSERVABLE INPUTS (LEVEL 3)
June 30, 2021				
Money market accounts	$ 102,788	$ 102,788	$ —	$ —
Total		$ 102,788	$ —	$ —
December 31, 2020				
Change of control derivative liability- related party	$ 16,849	$ —	$ —	$ 16,849
Convertible SAFEs - related party	9,727	—	—	9,727
Total		—	—	26,576

The Company did not have any instruments measured at fair value as of December 31, 2019.

The Company's convertible promissory notes contain a change in control feature which have been determined to meet the definition of a derivative ("Change of control derivative liability – related party"). Each reporting period the Company's remeasures the change of control derivative liability to its estimated fair value. To determine the estimated fair value of the Change of control derivative liability – related party, the Company uses a combination of probability analysis and Monte Carlo simulation methodology. Probabilities are used to establish a distribution of time to a financing or change of control and Monte Carlo simulation is used to forecast future equity values at the time of either event, which then are used to estimate the future values of the notes upon conversion or payout upon either event. The key inputs to the Monte Carlo simulation include inputs including the common stock price, volatility of common stock, the risk-free interest rate and the probability of conversion into common shares at the conversion rate in the event of a change in control or major transaction (e.g., liquidity). Fair value measurements are highly sensitive to changes in these inputs and significant changes could result in a significantly higher or lower fair value and resulting expense or gain.

During 2020, the Company also entered into various Simple Agreement for Future Equity Notes (Note 5). These Convertible SAFE Notes are accounted for as a liability in accordance with ASC 480, *Distinguishing Liabilities from Equity*, and are stated at fair value based on Level 3 inputs. The fair value of the Convertible SAFE Notes are based on a combination of probability analysis and Monte Carlo simulation methodology. Probabilities are used to establish a distribution of time to a financing or change of control and Monte Carlo simulation is used to forecast future equity values at the time of either event, which then are used to estimate the future values of the notes upon conversion or payout upon either event. The key inputs to the Monte Carlo simulation include inputs including the common stock price, volatility of common stock, the risk-free interest rate and the probability of conversion into common shares at the conversion rate in the event of a change in control or major transaction (e.g., liquidity). The Convertible SAFE Notes were initially recorded at an amount equal to the value of consideration received.

On February 26, 2021, the Company received $57.3 million in cash in connection with a Series A preferred stock financing. The Series A preferred stock financing agreement included a mutually agreed upon right for the same investors to purchase an additional $57.0 million in preferred stock and a related 4,850,428 shares of common stock in connection with a second closing of the same Series A preferred stock financing. The tranche right associated with the second closing of the Series A Preferred Stock was accounted for as a liability

("Tranche Liability"). On June 10, 2021, the Series A Preferred Stock investors exercised their right, and the Company received an additional $57.0 million in proceeds in the second closing of the Series A preferred stock financing (Note 7).

The following table summarizes the activity of this Level 3 liability (in thousands):

	CHANGE OF CONTROL DERIVATIVE LIABILITY - RELATED PARTY	CONVERTIBLE SAFE NOTES - RELATED PARTY	SERIES A TRANCHE LIABILITY
Balance at December 31, 2019	$ —	$ —	$ —
Issuance of debt instruments	—	6,128	—
Change in fair value	16,963	3,802	—
Modification of debt instruments with related party, net	(114)	(203)	—
Balance at December 31, 2020	16,849	9,727	—
Issuance of Series A tranche liability	—	—	1,552
Change in fair value	6,883	4,168	5,476
Conversion of Debt instruments to Series A-1 Preferred Stock	(23,732)	(13,895)	—
Conversion of Series A tranche liability to Series A Preferred Stock and common stock	—	—	(7,028)
Balance at June 30, 2021	$ —	$ —	$ —

The Company's policy is to recognize transfers between levels at the end of the reporting period. There were no transfers between Level 1, Level 2 or Level 3 during the years ended December 31, 2019 and 2020 and the six months ended June 30, 2021.

4. Consolidated Balance Sheet Details

Prepaid expenses consist of the following (in thousands):

	DECEMBER 31,		JUNE 30,
	2019	2020	2021
Prepaid research and development costs	$ 39	$ 1	$ 2,062
Prepaid other	—	—	161
Prepaid related party expenses	1	—	17
Total prepaid expenses	$ 40	$ 1	$ 2,240

Long term assets consist of the following (in thousands):

	DECEMBER 31,		JUNE 30,
	2019	2020	2021
Deferred offering costs	$ —	$ —	$ 753
Security deposits	—	—	63
Total other long-term assets	$ —	$ —	$ 816

Accrued liabilities consisted of the following (in thousands):

	DECEMBER 31,		JUNE 30,
	2019	2020	2021
Accrued research and development costs	$ 266	$ 234	$ 4,437
Other accrued liabilities	—	50	889
Accrued related party liabilities	3	17	365
Total accrued liabilities	$ 269	$ 301	$ 5,691

The Company had no capitalized property and equipment for the years ended December 31, 2019 and 2020. Property and equipment at June 30, 2021 consists of the following (in thousands):

	JUNE 30, 2021
Laboratory equipment	$ 56
Furniture and fixtures	10
Computer hardware and software	11
	77
Less: accumulated depreciation	(5)
Total	$ 72

Depreciation of property and equipment of $5 thousand was recorded for the six-month period ended June 30, 2021 (unaudited).

5. Acquisitions

In connection with the Series A preferred stock financing (Note 7), the Company acquired all of the outstanding equity and convertible debt interests of Oppilan Pharma Ltd. (“Oppilan”) and Zomagen Biosciences Ltd. (“Zomagen”). Certain investors of Oppilan and Zomagen are also investors of the Company and are considered related parties. Details of the acquisition are as follows:

- Pursuant to the terms of the Share Purchase Agreement (the “Oppilan Purchase Agreement”), upon closing, the Company issued to the shareholders of Oppilan 3,451,419 shares of Ventyx common stock, 38,727,626 shares of Series A-1 convertible preferred stock and options to purchase 726,546 shares of Ventyx common stock in exchange for all of the outstanding equity interest of Oppilan. Oppilan’s lead candidate, VTX002, is a modulator of the S1P receptor that has a unique pharmacokinetic and pharmacodynamic profile, recently completed phase 1 clinical testing.

- Pursuant to the terms of the Share Purchase Agreement (the "Zomagen Purchase Agreement"), upon closing, the Company issued to the shareholders of Zomagen 4,380,030 shares of Ventyx common stock, 19,164,836 shares of Series A-1 convertible preferred stock and options to purchase 291,577 shares of Ventyx common stock in exchange for all of the outstanding equity interest of Zomagen. Zomagen's lead candidate, VTX2735, is a pre-clinical stage program focused on high value targets of the NLRP3 inflammasome, targeting chronic inflammatory disorders.

As substantially all of the fair value of the gross assets acquired were in-process research and development intangible assets, the Company concluded that the acquisitions of Oppilan and Zomagen did not meet the definition of a business combination pursuant to FASB Accounting Standard Codification Topic 805, Business Combinations.

The fair value of the consideration provided in the acquisitions was $14.1 million and $7.8 million for Oppilan and Zomagen, respectively. The excess of the cost of acquisition over net assets acquired was $12.9 million and $8.9 million for Oppilan and Zomagen, respectively. Management determined that there is no alternative future use of the in-process research and development ("IPR&D") assets acquired, accordingly, the excess of the cost of acquisition over net assets acquired was expensed as IPR&D at the acquisition date.

The determination of the purchase price and related charge to IPR&D is as follows (in thousands):

	OPPILAN	ZOMAGEN	TOTAL
Net assets (liabilities) acquired	$ 1,170	$ (1,027)	$ 143
Fair value of shares issued	13,498	7,534	21,032
Transaction fees	370	207	577
Fair value of vested common stock options exchanged	225	90	315
Purchase price	14,093	7,831	21,924
Acquired IPR&D	$ 12,923	$ 8,858	$ 21,781

The Company is still finalizing the allocation of the purchase price, therefore, the purchase price allocation or the provisional measurements related to deferred income tax assets or liabilities may be adjusted if the Company recognizes additional assets or liabilities to reflect new information obtained about facts and circumstances that existed as of the acquisition date that, if known, would have affected the measurement of the amounts recognized as of that date. The Company expects to complete the allocation of purchase price during fiscal year 2021.

On February 7, 2019, the Company acquired all rights, title and interests related to compounds that inhibit tyrosine kinase2 (TYK2), from Vimalan Biosciences, Inc.("Vimalan"), in exchange for the assumption of $750,000 of Convertible Promissory Notes (Note 6), issued by New Science Ventures LLC ("NSV"). Raju Mohan, PhD., the Chief Executive Officer of the Company, is also the Chief Executive Officer of Vimalan and is affiliated with NSV. The Company determined that there is no alternative future use of the related compounds and recorded the value of the rights acquired of $750,000 as research and development expense during the year ended December 31, 2019.

6. Debt – Related Party

Convertible Promissory Notes-Related Party

Between February 2019 and December 2019, the Company issued $3.7 million of Convertible Promissory Notes ("Convertible Notes") to certain related parties, with maturity dates of 18 months from the issuance dates, including $750,000 of notes that were assumed in exchange for acquired technology (Note 5). The

Convertible Notes accrue interest at 6% per annum and are payable at maturity unless otherwise converted prior to maturity. The Convertible Notes are the Company's senior, unsecured obligations and are (i) equal in right of payment with the Company's future senior, unsecured indebtedness; (ii) senior in right of payment for the Company's future indebtedness; (iii) effectively subordinated to the Company's future secured indebtedness, to the extent of the value of the collateral securing that indebtedness; and (iv) structurally subordinated to all existing and future indebtedness and other liabilities, including trade payables.

The original terms of the Convertible Notes provide for the principal and unpaid accrued interest to automatically convert into the type of stock issued in a future qualified financing of at least $2.5 million, at a per share conversion price based on a pre-money valuation of the Company as mutually agreed upon by the Company and holders at the time of the financing, or at the holder's election, a per share conversion price equal to the price paid by investors in the financing. Upon the occurrence of a Change of Control (as specifically defined in the agreements), each holder may elect to redeem the Convertible Notes at a price equal to the outstanding principal plus unpaid accrued interest together with a premium equal to 100% of the outstanding principal. Upon the occurrence of an Event of Default (as specifically defined in the agreements), at the option and upon the declaration of the holder, the outstanding principal amount and unpaid accrued interest shall become due and payable. Notwithstanding the foregoing, the Convertible Notes are not redeemable by the Company prior to maturity without the explicit consent of the holder.

The Company evaluated the original notes for embedded features that might require bifurcation from the Convertible Notes. The ability for each Holder to elect to redeem the Convertible Notes upon a Change of Control resulted in a Change in Control Derivative Liability feature with a related party, that meets the definition of a derivative and requires bifurcation from the Convertible Notes.

As the Change in Control Derivative Liability feature is contingent upon a Change of Control occurring, the Company estimates the fair value based on the probability of such an occurrence. At each balance sheet date, the Company remeasures the fair value of the Change in Control Derivative Liability feature, with changes in fair value recognized as a component of other income (expense) in the Statements of Operations and Comprehensive Loss. At December 31, 2019, the Company concluded that the probability of a change of control continued to be remote, and therefore, recorded no change in fair value related to the Change in Control Derivative Liability feature.

In August 2020, the Company and holders amended the then outstanding Convertible Notes with a principal amount due of $3.7 million to (i) extend the maturity dates to February 2022; (ii) remove interest requirements; (iii) amend the Change of Control feature; and (iv) add an optional conversion feature (the "Amended Notes"). The amended Change of Control feature requires the Company to provide in a definitive acquisition agreement governing such event to provide that the holders will receive an aggregate of 69.75% of the proceeds that are otherwise payable or issuable to the Company's equity holders in such event. The amended conversion feature allows for, at the election of the holders, the right to convert the outstanding principal into an aggregate of 16,085,121 shares of fully paid and nonassessable shares of a newly created series of preferred stock of the Company, intended to represent 69.75% of the outstanding shares of capital stock of the Company on a fully-diluted basis.

The Company concluded that the amendment to the Convertible Notes in August 2020 represented an extinguishment. Given that the Holders of the Convertible Notes are a related party, the amendment was treated as a related party extinguishment of the original Convertible Notes and accounted for as a capital transaction. The Company recognized the difference between the carrying value of the notes as of the extinguishment date and the fair value post modification as a $1.4 million as an increase to additional-paid-in-capital during the year ended December 31, 2020.

The Company also evaluated the Amended Notes agreement for embedded features that might require bifurcation from the Amended Notes. The ability for each Holder to elect to redeem the Amended Notes upon a

Change of Control resulted in a Change in Control Derivative Liability feature that meets the definition of a derivative and requires bifurcation from the Amended Notes. The Company allocated a value of $1.0 million to the Change in Control Derivative Liability feature based on a probability assessment at the date of issuance as of the amendment date. The change in value of the Change in Control Derivative as a result of the extinguishment or $0.1 million was recorded as in increase to additional paid in capital.

At each balance sheet date, the Company remeasures the fair value of the Change in Control Derivative Liability feature, with changes in fair value recognized as a component of other income (expense) in the Statements of Operations and Comprehensive Loss. For the year ended December 31, 2020, the Company recorded an increase to the Change of Control Derivative Liability of $16.8 million (Note 3).

In February 2021, the Amended Convertible Notes converted into shares of the Company's Series A-1 Convertible Preferred Stock issued in conjunction with the Oppilan and Zomagen acquisitions (Note 7). Upon conversion the Company approved an in-substance amendment which allowed for the Holders to receive shares based upon the Change of Control terms of the Amended Convertible Promissory Note agreement, even though a change of control, as defined in the Amended Convertible Promissory Note agreement, had not been met. Management concluded that the amendment resulted in an instrument substantially different from the original, resulting in the overall transaction being accounted for as an extinguishment. The Company recorded a final fair value adjustment during the six months ended June 30, 2020 of $6.9 million based on the estimated fair value as of the extinguishment date. Upon extinguishment and conversion, the difference between the fair value of the Amended Notes and the Change of Control derivative of $26.7 million and the fair value of securities received of $31.4 million, was recorded as a reduction of $4.7 million to additional paid in capital, as the holders of the notes are related parties.

For the periods ended December 31, 2019 and 2020, interest expense recorded associated with the Convertible Notes was $0.1 million for both periods, respectively.

As of June 30, 2021, the Company had no long-term debt outstanding.

Convertible SAFE Notes – Related Party

From January 2020 through July 2020, the Company received $2.8 million of advances from several related party investors. In August 2020, the Company amended the terms of the advances, resulting in the Company entering into multiple Simple Agreement for Future Equity arrangements with the same related party investors. The amendment was accounted for as a modification and the Company recorded the difference between the carrying value and the fair value of the notes of $0.2 million as an increase to additional-paid-in-capital at the date of modification, as the holders of the SAFE Notes are related parties. The modified terms of these SAFE Notes are included below, and collectively referred to as the ("Convertible SAFE Notes").

January 2020 SAFE

In January 2020, the Company raised $200,000 by entering into a Simple Agreement for Future Equity ("January 2020 SAFE") with certain related party investors. The January 2020 SAFE has no maturity date and bears no interest. The holders of the January 2020 SAFE have the right, at the election of the holders, together with the Convertible Promissory Notes, to convert the January 2020 SAFE purchase amount and Convertible Promissory Notes' principal, into an aggregate of 16,085,121 shares of fully paid and nonassessable shares of a newly created series of preferred stock of the Company with a 1x liquidation preference.

Upon the occurrence of a sale of the Company or an Initial Public Offering, each holder may elect to require the Company to provide in the definitive acquisition agreement governing such event to provide that the holders will receive an aggregate of 69.75% of the proceeds that are otherwise payable or issuable to the Company's equity holders in such event. Upon an event of dissolution, the holders of the January 2020 SAFE would receive cash payment equal the purchase amount.

The Company determined that the January 2020 SAFE was not legal form debt (i.e., no creditors' rights) but allowed for redemption based upon certain events that are outside of the control of the Company. The January 2020 SAFE was classified as a marked-to-market liability pursuant to ASC 480, *Distinguishing Liabilities from Equity*. The January 2020 SAFE was measured at fair value at issuance and each reporting period, with changes in fair value recorded within the statements of operations (Note 3).

The January 2020 SAFE converted into 5,311,084 shares of the Company's Series A-1 Convertible Preferred Stock issued in February 2021 in conjunction with the Oppilan and Zomagen acquisitions referred to in the Organization and Basis of Presentation sections above.

February 2020 SAFE

In February 2020, the Company entered into a Simple Agreement for Future Equity ("February 2020 SAFE") with certain related parties that allowed for series of advances and raised $1.3 million between February 2020 and April 2020. The February 2020 SAFE has no maturity date and bears no interest. The holders of the February 2020 SAFE have the right upon a financing to convert the purchase amount automatically into the type of stock issued in the financing at a per share conversion price equal to the lowest price paid by investors in the financing. The holders of the February 2020 SAFE have a right upon conversion of the Convertible Notes to receive an aggregate of 7,501,754 shares of the existing Preferred Stock then authorized by the Company ("Equity Kicker").

Upon the occurrence of a sale of the Company or an Initial Public Offering, each holder may have elected to redeem the February 2020 SAFE at a price equal to the purchase amount. Upon sale of the company, in addition to receiving the purchase amount, each holder may have elected to receive the equity kicker or require the Company to provide in the definitive acquisition agreement governing such event to provide that the holders will receive an aggregate of 5.25% of the proceeds that are otherwise payable or issuable to the Company's equity holders in such event. Upon an event of dissolution, the holders of the February 2020 SAFE would receive cash payment equal the purchase amount.

The Company determined that the February 2020 SAFE was not legal form debt (i.e., no creditors' rights) but allowed for redemption based upon certain events that are outside of the control of the Company. The February 2020 SAFE was classified as a marked-to-market liability pursuant to ASC 480, *Distinguishing Liabilities from Equity*. The February 2020 SAFE was measured at fair value, with changes in fair value recorded within the statements of operations (Note 3).

The February 2020 SAFE converted into 8,826,754 shares of the Company's Series A-1 Convertible Preferred Stock issued in February 2021 in conjunction with the Oppilan and Zomagen acquisitions referred to in the Organization and Basis of Presentation sections above.

May 2020 SAFE

In May 2020, the Company entered into a Simple Agreement for Future Equity ("May 2020 SAFE") with investors that allowed for series of advances and raised $4.6 million between May 2020 and December 2020. The May 2020 SAFE has no maturity date and bears no interest. The holders of the May 2020 SAFE have the right to convert the purchase amount automatically into the type of stock issued in a qualified financing at a per share conversion price equal the lowest price paid by investors in the financing.

Upon the occurrence of a sale of the Company or an Initial Public Offering, each holder may elect to redeem the May 2020 SAFE at a price equal to the purchase amount together with a premium equal to the purchase amount. Upon an event of dissolution, the holders of the May 2020 SAFE would receive cash payment equal the purchase amount.

The Company determined that the May 2020 SAFE was not legal form debt (i.e., no creditors' rights) but allowed for redemption based upon certain events that are outside of the control of the Company. The May 2020 SAFE was classified as a marked-to-market liability pursuant to ASC 480, *Distinguishing Liabilities from*

Equity. The May 2020 SAFE was measured at fair value, with changes in fair value recorded within the statements of operations (Note 3).

The May 2020 SAFE converted into 9,205,000 shares of the Company's Series A-1 Convertible Preferred Stock issued in February 2021 in conjunction with the Oppilan and Zomagen acquisitions referred to in the Organization and Basis of Presentation sections above.

January 2021 SAFE

In January 2021, the Company raised $450,000 by entering into a Simple Agreement for Future Equity ("January 2021 SAFE") with certain related party investors. The January 2021 SAFE has no maturity date and bears no interest. The holders of the January 2021 SAFE have the right to convert the purchase amount automatically into the type of stock issued in a qualified financing at a per share conversion price equal the lowest price paid by investors in the financing.

Upon the occurrence of a sale of the Company or an Initial Public Offering, each holder may elect to redeem the January 2021 SAFE at a price equal to the purchase amount together with a premium equal to the purchase amount. Upon an event of dissolution, the holders of the January 2021 SAFE would receive cash payment equal the purchase amount.

The Company determined that the January 2021 SAFE was not legal form debt (i.e., no creditors' rights) but allowed for redemption based upon certain events that are outside of the control of the Company. The January 2021 SAFE was classified as a marked-to-market liability pursuant to ASC 480, *Distinguishing Liabilities from Equity*. The January 2021 SAFE was measured at fair value, with changes in fair value recorded within the statements of operations (Note 3).

The January 2021 SAFE converted into 471,966 shares of the Company's Series A Convertible Preferred Stock issued in February 2021 in conjunction with the Oppilan and Zomagen acquisitions.

7. Convertible Preferred Stock and Contingencies

Series A Convertible Preferred Shares

On February 26, 2021, the Company received gross proceeds of $57.3 million in cash in connection with its Series A Preferred Stock financing from various related party investors. The Company issued 60,097,042 shares at a purchase price of $0.9534578 per share. The Company incurred issuance costs related to its Series A Preferred Stock financing of $0.4 million, which were recorded as a reduction of the total proceeds. The Series A purchase agreement allowed the original investors to purchase an additional 59,782,399 shares of Series A Convertible Preferred Shares (the "Additional Shares"), on the same terms and conditions as the original issuance at the original issue price of $0.9534578 per share (the "Second Closing" or "Tranche Liability") upon the election of at least a majority of the then outstanding shares. On June 10, 2021, the Series A Preferred Stock investors exercised their right to purchase the Additional Shares, and the Company received an additional $57.0 million in proceeds in the second closing of the Series A preferred stock financing. The Series A Preferred Stock has a $0.0001 par value.

Deemed Dividend

On February 26, 2021, in connection with the $57.3 million in cash received with the Series A preferred stock financing, the Company issued 4.9 million incremental common shares to a Series A investor. The fair value of the incremental common shares of $1.6 million was treated as a deemed dividend during the six-month period ended June 30, 2021. The deemed dividend is reflected on the face of the consolidated statement of

operations and comprehensive loss for the six months ended June 30, 2021 as a reduction to net loss to arrive at net loss attributable to common shareholders.

Series A Convertible Preferred Shares – Tranche Liability

The rights and preferences of the Series A Convertible Preferred Stock sold under the two tranches have the same rights and preferences. The Company concluded that these rights or obligations of the investors to participate in tranches of Series A convertible preferred shares met the definition of a freestanding financial instrument that was required to be recorded as a liability at fair value as (i) the instruments are legally detachable and separately exercisable from the Series A convertible preferred shares and (ii) the rights will require the Company to transfer assets upon future closings of the Series A convertible preferred shares. In addition, the company is obligated to issue 4,850,428 shares of common stock to a Series A investor if they participate in the second tranche. Given the common shares were linked to the second tranche, they were also considered a component of the Tranche Liability. Upon the closing of the Series A Convertible Preferred Stock financing in February 2021, the fair value of the tranche right was $1.5 million. On June 10, 2021, the Series A Preferred Stock investors exercised their right and the Company received an additional $57.0 million in proceeds in the second closing of the Series A Preferred Stock Financing. The Company recorded a change in fair value of the Series A Tranche Liability of $5.5 million, which was recognized in the Company's Statement of Operations and Comprehensive Loss for the six-month period ended June 30, 2021.

Dividends

The holders of then outstanding shares of Series A Convertible Preferred Stock shall be entitled to receive, only when, as and if declared by the Board of Directors, out of any funds and assets legally available therefore, dividends at the rate of 8.0% of the original issue price of $0.9534578 per share for each share of Series A Convertible Preferred Stock, prior and in preference to any declaration or payment of any other dividend (other than dividends on shares of Common Stock payable in shares of Common Stock). The right to receive dividends on shares of Series A Convertible Preferred Stock pursuant to the preceding sentence shall not be cumulative, and no right to dividends shall accrue to holders of Series A Convertible Preferred Stock by reason of the fact that dividends on said shares are not declared. No dividends have been declared as of June 30, 2021.

Liquidation

In the event of (a) any voluntary or involuntary liquidation, dissolution or winding up of the Company, the holders of shares of Series A Convertible Preferred Stock then outstanding shall be entitled to be paid out of the assets of the Company available for distribution to its stockholders, and (b) a deemed liquidation event, the holders of shares of Series A Convertible Preferred Stock then outstanding shall be entitled to be paid out of the consideration payable to stockholders in such deemed liquidation event or out of the available proceeds, as applicable, on a pari passu basis among each other, before any payment shall be made to the holders of Series A-1 Convertible Preferred Stock or Common Stock by reason of their ownership thereof, an amount per share equal to one times $0.9534578, plus any dividends declared but unpaid thereon. If, upon any such liquidation, dissolution or winding up of the Company or deemed liquidation event, the assets of the Company available for distribution to its stockholders shall be insufficient to pay the holders of shares of Series A Convertible Preferred Stock the full amount to which they shall be entitled, the holders of shares of Series A Convertible Preferred Stock shall share ratably in any distribution of the assets available for distribution in proportion to the respective amounts which would otherwise be payable in respect of the shares held by them upon such distribution if all amounts payable on or with respect to such shares were paid in full.

In the event of (a) any voluntary or involuntary liquidation, dissolution or winding up of the Company, after the payment in full of all preferred liquidation amounts required to be paid to the holders of shares of Series A Convertible Preferred Stock the remaining assets of the Company available for distribution to its stockholders and not payable to the holders of Series A Convertible Preferred Stock as defined above, or (b) a deemed liquidation event, after the payment in full of all preferred liquidation amounts required to be paid to the holders of shares of Series A Convertible Preferred Stock the consideration available for distribution to the stockholders of the Company and not payable to the holders of shares of Series A Convertible Preferred Stock, or the

available proceeds not payable to the holders of shares of Series A Convertible Preferred Stock pursuant to the preceding paragraph, as the case may be, shall be distributed among the holders of the shares of Series A Convertible Preferred Stock, Series A-1 Convertible Preferred Stock and Common stock, pro rata based on the number of shares held by each such holder, treating for this purpose all such shares of Series A Convertible Preferred Stock and Series A-1 Convertible Preferred Stock as if they had been converted to Common Stock pursuant to the terms of the Amended Articles of Incorporation immediately prior to such liquidation, dissolution or winding up of the Company or such deemed liquidation event.

Conversion

Each share of Series A Convertible Preferred Stock shall be convertible, at the option of the holder thereof, at any time and from time to time, and without the payment of additional consideration by the holder thereof, into such number of fully paid and non-assessable shares of Common Stock as is determined by dividing the original issue price of $0.9534578 by the applicable conversion price in effect at the time of conversion, provided that such holder may waive such option to convert upon written notice to the Company. The conversion price shall initially be equal to $0.9534578 and is subject to adjustment.

In the event of a liquidation, dissolution or winding up of the Company or a deemed liquidation event, the conversion rights shall terminate at the close of business on the last full day preceding the date fixed for the payment of any such amounts distributable on such event to the holders of Series A Convertible Preferred Stock, provided that the foregoing termination of conversion rights shall not affect the amount otherwise paid or payable to holders of Series A Convertible Preferred Stock pursuant to such liquidation, dissolution or winding up of the Company or a deemed liquidation event.

Upon either (a) the closing of the sale of shares of Common Stock to the public at a price of at least $1.24 per share (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Common Stock) in a firm-commitment underwritten public offering pursuant to an effective registration statement under the Securities Act of 1933, as amended, resulting in at least $75,000,000 of gross proceeds to the Company and in connection with such offering the Common Stock is listed for trading on the Nasdaq Stock Market's National Market, the New York Stock Exchange or another exchange or marketplace approved by the Board of Director, or (b) the date and time, or the occurrence of an event, specified by vote or written consent of the Requisite Holders, then (i) all outstanding shares of Series A Convertible Preferred Stock shall automatically be converted into shares of Common Stock, at the then effective conversion rate as calculated and (ii) such shares may not be reissued by the Company.

Voting Rights

On any matter presented to the stockholders of the Company for their action or consideration at any meeting of stockholders of the Company, each holder of outstanding shares of Series A Preferred Stock shall be entitled to cast the number of votes equal to the number of whole shares of Common Stock into which the shares of Series A Convertible Preferred Stock held by such holder are convertible as of the record date for determining stockholders entitled to vote on such matter. Except as provided by law or by the other provisions of the Amended Articles of Incorporation, holders of Series A Convertible Preferred Stock shall vote together with the holders of Common Stock as a single class and on an as-converted to Common Stock basis.

Redemption

The shares of Series A Convertible Preferred Stock shall not be redeemable by any holder thereof.

Series A-1 Convertible Preferred Shares

On February 26, 2021, the Company issued 38,727,626 and 19,164,836 shares of Series A-1 Convertible Preferred Stock to the former equity and debt security holders of Oppilan and Zomagen, respectively. Additionally, on February 26, 2021, the Company issued 121,597,908 shares of Series A-1 Convertible Preferred Stock upon the conversion of Convertible Notes and Convertible SAFE Notes with a principal amount outstanding of $9.8 million (See Note 6).

Dividends

The Company shall not declare, pay or set aside any dividends on shares of Series A-1 Convertible Preferred Stock, Common Stock or any other class or series of capital stock of the Company (other than dividends on shares of Common Stock payable in shares of Common Stock).

Liquidation

In the event of (a) any voluntary or involuntary liquidation, dissolution or winding up of the Company, after the payment in full of all preferred liquidation amounts required to be paid to the holders of shares of Series A Convertible Preferred Stock the remaining assets of the Company available for distribution to its stockholders and not payable to the holders of Series A Convertible Preferred Stock as described above, or (b) a deemed liquidation event, after the payment in full of all preferred liquidation amounts required to be paid to the holders of shares of Series A Convertible Preferred Stock the consideration available for distribution to the stockholders of the Company and not payable to the holders of shares of Series A Convertible Preferred Stock, or the available proceeds not payable to the holders of shares of Series A Convertible Preferred Stock as described above, as the case may be, shall be distributed among the holders of the shares of Series A Convertible Preferred Stock, Series A-1 Convertible Preferred Stock and Common stock, pro rata based on the number of shares held by each such holder, treating for this purpose all such shares of Series A Convertible Preferred Stock and Series A-1 Convertible Preferred Stock as if they had been converted to Common Stock pursuant to the terms of the Amended Articles of Incorporation immediately prior to such liquidation, dissolution or winding up of the Company or such deemed liquidation event.

Conversion

Each share of Series A-1 Convertible Preferred Stock shall be convertible, at the option of the holder thereof, at any time and from time to time, and without the payment of additional consideration by the holder thereof, into such number of fully paid and non-assessable shares of Common Stock as is determined by dividing $1.00 by the applicable conversion price in effect at the time of conversion, provided that such holder may waive such option to convert upon written notice to the Company. The conversion price shall initially be equal to $1.00 and is subject to adjustment in the event the Company issues additional shares of common stock, without consideration or for a consideration per share less than the conversion price of the Series A-1 Convertible Preferred Stock in effect immediately prior to such issuance or deemed issuance.

In the event of a liquidation, dissolution or winding up of the Company or a deemed liquidation event, the conversion rights shall terminate at the close of business on the last full day preceding the date fixed for the payment of any such amounts distributable on such event to the holders of Series A-1 Convertible Preferred Stock, provided that the foregoing termination of conversion rights shall not affect the amount otherwise paid or payable to holders of Series A-1 Convertible Preferred Stock pursuant to such liquidation, dissolution or winding up of the Company or a deemed liquidation event.

Upon either (a) the closing of the sale of shares of Common Stock to the public at a price of at least $1.24 per share (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Common Stock), in a firm-commitment underwritten public offering pursuant to an effective registration statement under the Securities Act of 1933, as amended, resulting in at least $75,000,000 of gross proceeds to the Company and in connection with such offering the Common Stock is listed for trading on the Nasdaq Stock market's National Market, the New York Stock Exchange or another exchange or marketplace approved by the Board of Directors, or (b) the date and time, or the occurrence of an event, specified by vote or written consent of the Requisite Holders, then (i) all outstanding shares of Series A-1 Convertible Preferred Stock shall automatically be converted into shares of Common Stock, at the then effective conversion rate as calculated and (ii) such shares may not be reissued by the Company.

Voting Rights

On any matter presented to the stockholders of the Company for their action or consideration at any meeting of stockholders of the Company, each holder of outstanding shares of Series A-1 Preferred Stock shall be entitled to cast the number of votes equal to the number of whole shares of Common Stock into which the shares of

Series A-1 Preferred Stock held by such holder are convertible as of the record date for determining stockholders entitled to vote on such matter. Except as provided by law or by the other provisions of the Amended Articles of Incorporation, holders of Preferred Stock shall vote together with the holders of Common Stock as a single class and on an as-converted to Common Stock basis.

Redemption

The shares of Series A-1 Convertible Preferred Stock shall not be redeemable by any holder thereof.

Litigation

From time to time, the Company may be involved in disputes, including litigation, relating to claims arising out of operations in the normal course of business. Any of these claims could subject us to costly legal expenses and, while management generally believe that the Company has adequate insurance to cover many different types of liabilities, the Company's insurance carriers may deny coverage, or the Company's policy limits may be inadequate to fully satisfy any damage awards or settlements. If this were to happen, the payment of any such awards could have a material adverse effect on the Company's results of operations and financial position. Additionally, any such claims, whether or not successful, could damage the Company's reputation and business. The Company currently is not a party to any legal proceedings, the adverse outcome of which, in management's opinion, individually or in the aggregate, would have a material adverse effect on the Company's results of operations or financial position.

8. Stockholders' Deficit

Common Stock

The Company is authorized to issue up to 47,603,832 shares of common stock each having a par value of $0.0001 as of December 31, 2019 and 2020, and 365,000,000 shares of common stock each having a par value of $0.0001 as of June 30, 2021. Holders of outstanding shares of common stock are entitled to one vote for each share of common stock held at all meetings of stockholders. However, they are not entitled to vote on any amendment to the amended Articles of Incorporation that relates solely to the terms of one or more outstanding series of preferred stock if the holders of such affected series are entitled to vote thereon. Subject to the rights of the holders of any class of the Company's capital stock having any preference or priority over common stock, the holders of common stock are entitled to receive dividends that are declared by the Company's board of directors out of legally available funds.

Common stock reserved for future issuance is as follows (in common stock equivalent shares) as of December 31, 2019, 2020 and June 30, 2021:

	DECEMBER 31,	
	2019	2020
Stock options issued and outstanding	7,451,315	14,803,421
Authorized for future option grants	17,602,405	10,018,901
Total common stock reserved for future issuance	25,053,720	24,822,322

	JUNE 30, 2021
Stock options issued and outstanding	23,357,778
Authorized for future option grants	1,344,597
Shares issuable upon conversion of Series A and A-1 preferred stock	299,369,811
Total common stock reserved for future issuance	324,072,186

9. Leases

In February 2021, the Company assumed a lease with a lease termination date of November 30, 2021 from a related party.

In June 2021, the Company signed a five year lease amendment and renewal which added an additional term and additional suites in the office building. The non-cancelable lease is effective July 1, 2021 and ends June 30, 2026.

There were no future minimum payments as of December 31, 2020. Future minimum payments under operating leases as of June 30, 2021 (in thousands) was:

	OPERATING LEASES
Years Ending December 31:	
2021 remaining	$ 165
2022	331
2023	331
2024	296
2025 and thereafter	391
	$ 1,514

10. Equity Incentive Plan

In February 2019, the Company adopted its 2019 Equity Incentive Plan (the Plan). The Plan provides for the grant of incentive stock options, non-statutory stock options, and restricted stock awards to employees, directors or consultants of the Company. The Plan provides that the maximum aggregate number of shares of the Company's common stock reserved and available for issuance under the Plan is 25,130,856. Options granted under the Plan generally vest over a period of 3 years, as determined by the Board of Directors, and the maximum term of stock options granted under the Plan is 10 years. As of December 31, 2019 and 2020 and June 30, 2021, the Company had 25,130,856 shares authorized for issuance under the Plan and 17,602,405, 10,018,901 and 1,344,597 shares, respectively, remained available for grant.

Stock Options

The following table summarizes stock option activity for the year ending December 31, 2020 and the six months ended June 30, 2021 (unaudited):

	NUMBER OF OPTIONS	WEIGHTED AVERAGE EXERCISE PRICE	AVERAGE REMAINING CONTRATUAL LIFE	TOTAL AGGREGATE INTRINSIC VALUE (IN THOUSANDS)
Outstanding at December 31, 2019	7,451,315	$ 0.02	9.15	$ 75
Granted	7,814,915	0.02		
Exercised	(231,405)	0.02		
Canceled/Forfeited	(231,404)	0.02		
Outstanding at December 31, 2020	14,803,421	$ 0.02	8.76	$ 299
Granted	8,674,304	0.34		
Exercised	(119,947)	(0.21)		
Canceled/Forfeited	—	—		
Outstanding at June 30, 2021	23,357,778	$ 0.14	8.84	$ 11,441
Vested and expected to vest at June 30, 2021 (unaudited)	9,250,318	$ 0.04	8.21	$ 9,374
Exercisable at June 30, 2021 (unaudited)	9,250,318	$ 0.04	8.21	$ 9,374

The intrinsic value of a stock option or restricted unit is the difference between the market price of the common stock at measurement date and the exercise price of the option. The weighted average grant date fair value of stock options granted during the years ended December 31, 2019, 2020 and the six months ended June 30, 2020 and 2021 were $0.01, $0.01, $.01 and $0.34, respectively, per share. The total intrinsic value of stock options exercised during the years ended December 31, 2019, 2020 and the six months ended June 30, 2020 and 2021 were $0, $1,700, $1,700 and $75,566, respectively.

As of December 31, 2019, 2020 and June 30, 2021, total unrecognized stock-based compensation costs related to unvested employee stock options was $124,300, $89,800 and $2,852,102, respectively, and is expected to be recognized over the weighted average period of approximately 2.14, 1.76 and 3.0 years, respectively, on a straight-line basis.

The following assumptions were used to estimate the fair value of stock option and restricted stock awards granted to employees under the Company's equity incentive plan during the periods presented:

	YEARS ENDED, DECEMBER 31,		SIX MONTHS ENDED JUNE 30,	
ASSUMPTION	2019	2020	2020	2021
			(unaudited)	
Expected volatility	80.00%	80.00%	80.00%	80.00%
Expected term (years)	5.77	5.77	5.77	5.77
Expected dividend yield	0.00%	0.00%	0.00%	0.00%
Risk-free interest rate	2.43%	1.62%	1.62%	1.41%
Forfeiture rate	0.00%	0.00%	0.00%	0.00%

The risk-free interest rate assumption was based on the United States Treasury's rates for U.S. Treasury zero-coupon bonds with maturities similar to those of the expected term of the award being valued. The assumed dividend yield was based on the Company's expectation of not paying dividends in the foreseeable future. For awards granted to nonemployees, the full remaining contractual term is used. The estimated volatility reflects an average volatility of comparable companies whose share prices are publicly available, adjusted to align with the current stage of development for the Company.

Restricted Stock Units

The Company grants restricted stock pursuant to the 2019 Plan and satisfies such grants through the issuance of new shares. Restricted stock awards generally vest over a period of three years. The total fair value of restricted stock awards vested during the years ended December 31, 2019, 2020 and the six months ended June 30, 2020 and 2021 was $185,000, $10,500 and $5,328, $1,663,199, respectively. Upon the termination of service of a restricted stockholder, the Company has the option to repurchase any unvested shares. During the years ending December 31, 2019 and 2020 and the six months ended June 30, 2021, the Company repurchased 424,247, 115,704 and 0 shares, respectively.

The following table summarizes restricted stock unit activity:

	NUMBER OF SHARES	WEIGHTED AVERAGE GRANT DATE FAIR VALUE
Balance at December 31, 2018	—	
Granted	21,150,646	$ 0.08
Vested	(18,348,687)	$ 0.08
Canceled / Forfeited	(424,247)	$ 0.08
Unvested Balance at December 31, 2019	2,377,712	$ 0.08
Vested	(1,037,477)	$ 0.08
Canceled / Forfeited	(115,704)	$ 0.08
Unvested Balance at December 31, 2020	1,224,531	$ 0.08
Granted	911,450	$ 0.36
Vested	(489,813)	$ 0.08
Unvested Balance at June 30, 2021	1,646,168	$ 0.24

The Company has recorded an immaterial amount for the years ended December 31, 2019 and 2020 and the six months ended June 30, 2021, respectively related to the unvested restricted stock awards subject to repurchase. The Company reduced the liability as the underlying shares vested.

Stock-based compensation expense has been reported in the Company's statements of operations as follows (in thousands):

	YEARS ENDED, DECEMBER 31,		SIX MONTHS ENDED JUNE 30,	
	2019	2020	2020	2021
Research and development	$ 38	$ 29	$ 11	$ 230
General and administrative	160	16	6	138
Total stock-based compensation	$ 198	$ 45	$ 17	$ 368

As of June 30, 2021, there was approximately $326,000 of total unrecognized stock-based compensation cost related to non-vested restricted stock granted under the Plan. This cost is expected to be recognized over a weighted-average period of 3.0 years.

11. Employee Benefit Plan

Effective March 1, 2021, the Company assumed a defined contribution 401(k) plan from a related party - Kalika Biosciences, Inc. (Note 12) for employees who are at least 21 years of age. Employees are eligible to participate in the plan beginning on the first day of the calendar quarter following date of hire. Under the terms of the plan, employees may make voluntary contributions as a percent of compensation. No matching contributions have been made by the Company as of June 30, 2021, since the adoption of the 401(k) plan.

12. Income Taxes

A reconciliation of the federal statutory rate to the effective tax rate for loss from continuing operations for the years ended December 31, 2019 and 2020, respectively, is comprised as follows:

	YEARS ENDED DECEMBER 31,	
	2019	2020
(% of pre—tax loss)		
Statutory federal income tax rate	21.0%	21.0%
Convertible notes	-0.7%	-15.7%
Other	-1.0%	0.0%
Valuation allowance	-19.3%	-5.2%
Effective income tax rate	0.0%	0.0%

Significant components of the deferred tax balances at December 31, 2019 and 2020 are presented below (in thousands):

	YEARS ENDED DECEMBER 31,	
	2019	2020
Deferred tax balances		
Net operating losses	$ 836	$ 2,307
Valuation allowance	(836)	(2,307)
Total deferred tax balances, net of valuation allowance	$ —	$ —

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amount of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. The Company maintains a valuation allowance for its net deferred tax assets due to the uncertainty that such assets will be realized and evaluates the recoverability of its deferred tax assets on at least an annual basis. The Company has determined that its deferred tax assets are not realizable due to a lack of certainty regarding projected future profits.

For the years ended December 31, 2019 and 2020, the Company had federal net operating loss (“NOL”) carryforwards of $4.0 million and $11.0 million, respectively. The losses do not expire, but are limited to 80% utilization against taxable income.

Pursuant to Internal Revenue Code ("IRC") of 1986, as amended specifically IRC Section 382, the Company's ability to use U.S. net operating loss carryforwards to offset future taxable income is limited if the Company experiences a cumulative change in ownership of more than 50% within a three-year testing period. The Company has not completed an ownership change analysis pursuant to IRC Section 382. If ownership changes within the meaning of IRC Section 382 are identified as having occurred, the amount of remaining net operating loss carryforwards available to offset future taxable income and income tax expense in future years may be significantly restricted.

As of December 31, 2020, there were no significant unrecognized tax benefits, and no significant changes to unrecognized tax benefits are expected in the following 12 months. The Company's policy is to classify any interest and penalties as a component of income tax expense, if applicable. The Company had no accrued interest or penalties related to income tax matters on its balance sheets at December 31, 2019 or 2020, and has not recognized interest or penalties in its consolidated statements of operations and comprehensive loss for the years ended December 31, 2019 and 2020, respectively. Further, the Company is not currently under examination by any federal, state, or local tax authority.

On March 27, 2020, the Coronavirus Aid, Relief and Economic Security ("CARES") Act was signed into law. The CARES Act is an emergency economic stimulus package that includes spending and tax breaks to strengthen the U.S. economy and fund a nationwide effort to curtail the effect of COVID-19. While the CARES Act provides sweeping tax changes in response to the COVID-19 pandemic, some of the more significant provisions which may impact the Company's future financial statements include removal of certain limitations on utilization of NOLs, increasing the loss carryback period for certain losses to five years, as well as amending certain provisions of the previously enacted JOBS Act. The Company has not recognized the provisional tax impacts related to the CARES Act in relation to its financial statements for the year ended December 31, 2020.

13. Related Party Transactions

On February 7, 2019, the Company acquired all rights, title and interests related to compounds that inhibit tyrosine kinase2 (TYK2), from Vimalan Biosciences, Inc.("Vimalan"), in exchange for the assumption of $750,000 of Convertible Promissory Notes (Note 6), issued by funds of New Science Ventures LLC ("NSV"). Raju Mohan, PhD., the Chief Executive Officer of the Company, is also the Chief Executive Officer of Vimalan and is affiliated with NSV. The Company determined that there is no alternative future use of the related compounds and recorded the value of the rights acquired of $750,000 as research and development expense during the year ended December 31, 2019.

On January 1, 2019, the Company entered into a Support Services Agreement with Kalika Biosciences, Inc. ("Kalika") that outlines the terms of services provided by Kalika to the Company, as well as the fees charged for such services. Kalika is a shared service company that provides certain administrative and research and development support services, including facilities support and office space. Kalika is beneficially owned by Raju Mohan, PhD., the Chief Executive Officer of Ventyx, and NSV, which is affiliated with both a non-employee director and funds of NSV, which are owners of more than 5% of the Company's capital stock. The Company pays Kalika monthly for costs incurred under the agreement. Either party may terminate the support services agreement by giving 30 days' prior notice. On March 1, 2021, in conjunction with the acquisition of Oppilan Ltd and Zomagen Ltd, the Company terminated the agreement with Kalika and transitioned all employees of Kalika to the Company.

On October 17, 2019, the Company entered into a Research and Development Support Services Agreement with Bayside Pharma, LLC ("Bayside") that outlines the terms of services provided by Bayside to the Company, as well as the fees charged for such services. Bayside is a research and development services company that provides certain research and development support services and facilities. Bayside is owned by an employee of the Company. The Company pays Bayside monthly for costs incurred under the agreement. Either party may terminate the support services agreement by giving 30 days' prior notice.

Expense recognized by the Company under the related party Support Services Agreements was as follows (in thousands):

	YEARS ENDED DECEMBER 31,		SIX MONTHS ENDED JUNE 30,	
	2019	2020	2020	2021
Research and development—Kalika	$ 471	$ 553	$ 277	$ 112
Research and development—Bayside	903	412	370	350
Total research and development—related party	$ 1,374	$ 965	$ 647	$ 462
General and administrative—Kalika	296	400	221	116
Total general and administrative—related party	$ 296	$ 400	$ 221	$ 116

At December 31, 2019 and 2020, the Company had accounts payable and accrued expenses due to related parties of $73,358 and $255,323, respectively. At June 30, 2021, the Company had prepaid expenses to related parties of $17,215 and accounts payable and accrued expenses due to related parties of $365,430.

14. Subsequent Events

The Company has evaluated all subsequent events through August 20, 2021, the date the consolidated financial statements for the years ended December 31, 2019 and 2020 and for the six months ended June 30, 2021 were issued.

On July 29, 2021, the Board of Directors approved an increase in the option pool by 19.2 million shares and also approved the issuance of 11.2 million stock option grants at an exercise price of $0.63 per share.

CONSOLIDATED FINANCIAL STATEMENTS

OPPILAN PHARMA, LTD.

Years Ended May 31, 2019 and 2020
With Report of Independent Auditors

REPORT OF INDEPENDENT AUDITORS

To management and the Board of Directors
Oppilan Pharma, Ltd.

We have audited the accompanying consolidated financial statements of Oppilan Pharma, Ltd., which comprise the consolidated balance sheets as of May 31, 2019 and 2020, and the related statements of operations, changes in convertible preferred shares and shareholders' deficit and cash flows for the years then ended, and the related notes to the consolidated financial statements.

Management's Responsibility for the Financial Statements

Management is responsible for the preparation and fair presentation of these financial statements in conformity with U.S. generally accepted accounting principles; this includes the design, implementation and maintenance of internal control relevant to the preparation and fair presentation of financial statements that are free of material misstatement, whether due to fraud or error.

Auditor's Responsibility

Our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the financial statements. The procedures selected depend on the auditor's judgment, including the assessment of the risks of material misstatement of the financial statements, whether due to fraud or error. In making those risk assessments, the auditor considers internal control relevant to the entity's preparation and fair presentation of the financial statements in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity's internal control. Accordingly, we express no such opinion. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of significant accounting estimates made by management, as well as evaluating the overall presentation of the financial statements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

Opinion

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Oppilan Pharma, Ltd. at May 31, 2019 and 2020, and the consolidated results of its operations and its cash flows for the years then ended in conformity with U.S. generally accepted accounting principles.

/s/ Ernst & Young LLP

San Diego, California
August 20, 2021

OPPILAN PHARMA, LTD

Consolidated Balance Sheets
(in thousands except share and nominal value amounts)

	MAY 31,	
	2019	**2020**
Assets		
Current assets:		
Cash and cash equivalents	$ 3,746	$ 1,359
Prepaid expenses and other assets (includes related party amounts of $216 and $8, respectively)	750	214
Total current assets	4,496	1,573
Property and equipment, net	18	13
Other long-term assets	9	—
Total assets	$ 4,523	$ 1,586
Liabilities, convertible preferred shares and shareholders' deficit		
Current liabilities:		
Accounts payable (includes related party amounts of $96 and $114, respectively)	$ 521	$ 141
Accrued expenses (includes related party amounts of $ 0 and $9, respectively)	268	505
2020 Bridge loan notes at fair value - related parties	—	2,307
Total current liabilities	789	2,953
Total liabilities	789	2,953
Commitments and contingencies		
Convertible preferred shares:		
Series A convertible preferred shares, $0.001 nominal value; 5,250,000 shares authorized, issued and outstanding at May 31, 2019 and 2020; liquidation preference of $498 at May 31, 2019 and 2020	500	500
Series B convertible preferred shares, $0.001 nominal value; 19,150,000 shares authorized at May 31, 2019 and 2020; 16,500,000 shares issued and outstanding at May 31, 2019 and 2020; liquidation preference of $16,500 at May 31, 2019 and 2020	16,391	16,391
Shareholders' deficit:		
Share Capital of $0.001 nominal value; 4,513,752 and 4,526,158 ordinary shares authorized and issued at May 31, 2019 and 2020, respectively; 4,430,002 and 4,526,158 outstanding at May 31, 2019 and 2020, respectively	4	5
Additional paid-in capital	588	623
Accumulated other comprehensive income	4	4
Accumulated deficit	(13,753)	(18,890)
Total shareholders' deficit	(13,157)	(18,258)
Total liabilities, convertible preferred shares and shareholders' deficit	$ 4,523	$ 1,586

See accompanying notes

OPPILAN PHARMA, LTD

Consolidated Statements of Operations and Comprehensive Loss
(in thousands)

	YEARS ENDED MAY 31,	
	2019	2020
Operating expenses:		
Research and development (includes related party amounts of $146 and $388, respectively)	$ 4,354	$ 4,064
General and administrative (includes related party amounts of $257 and $903, respectively)	802	1,264
Total operating expenses	5,156	5,328
Loss from operations	(5,156)	(5,328)
Other income (expense):		
Interest expense	(56)	—
Other expense	(41)	(2)
Change in fair value of 2020 Bridge Loan Notes - related parties	—	193
Net loss	(5,253)	(5,137)
Other comprehensive (loss) income		
Foreign currency translation	4	—
Comprehensive loss	$ (5,249)	$ (5,137)

See accompanying notes

OPPILAN PHARMA, LTD

Consolidated Statements of Convertible Preferred Shares and Shareholders' Deficit
(in thousands, except share amounts)

	SERIES A CONVERTIBLE PREFERRED SHARES		SERIES B CONVERTIBLE PREFERRED SHARES		ORDINARY SHARES		ADDITIONAL PAID-IN CAPITAL	ACCUMULATLED OTHER COMPREHENSIVE INCOME	ACCUMULATED DEFICIT	TOTAL SHAREHOLDERS DEFICIT
	SHARES	AMOUNT	SHARES	AMOUNT	SHARES	AMOUNT				
Balance at May 31, 2018	5,250,000	$ 500	7,500,000	$ 7,393	3,977,130	$ 4	$ 522		$ (8,500)	$ (7,974)
Issuance of convertible preferred shares for conversion of 2018 Bridge Loan Notes	—	—	2,156,336	2,156	—	—	—	—	—	—
Issuance of convertible preferred shares - net of offering costs of $1,589	—	—	6,843,664	6,842	—	—	—	—	—	—
Vesting of restricted ordinary shares	—	—	—	—	434,261	—	—	—	—	—
Issuance of ordinary shares upon exercise of stock options	—	—	—	—	18,611	—	2	—	—	2
Stock-based compensation	—	—	—	—	—	—	64	—	—	64
Foreign currency translation	—	—	—	—	—	—	—	4	—	4
Net loss	—	—	—	—	—	—	—	—	(5,253)	(5,253)
Balance at May 31, 2019	5,250,000	$ 500	16,500,000	$ 16,391	4,430,002	$ 4	588	4	$ (13,753)	$ (13,157)
Vesting of restricted ordinary shares	—	—	—	—	83,750	1	—	—	—	1
Issuance of ordinary shares upon exercise of stock options	—	—	—	—	12,406	—	2	—	—	2
Stock-based compensation	—	—	—	—	—	—	33	—	—	33
Net loss	—	—	—	—	—	—	—	—	(5,137)	(5,137)
Balance at May 31, 2020	5,250,000	$ 500	16,500,000	$ 16,391	4,526,158	$ 5	$ 623	$ 4	$ (18,890)	$ (18,258)

See accompanying notes

OPPILAN PHARMA, LTD

Consolidated Statements of Cash Flows
(in thousands)

	YEARS ENDED MAY 31,	
	2019	**2020**
Net loss	$ (5,253)	$ (5,137)
Operating activities		
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	10	5
Interest expense	56	—
Stock-based compensation	64	33
Foreign exchange (gain) on operating cash flows	4	—
Change in fair value of 2020 Bridge Loan Notes - related parties	—	(193)
Changes in operating assets and liabilities:		
Prepaid expenses and other assets (includes related party amounts of ($216) and $208, respectively)	(364)	545
Accounts payable	377	(397)
Accrued expenses (includes related party amounts of $96 and $27, respectively)	169	255
Net cash used in operating activities	(4,937)	(4,889)
Investing activities		
Purchases of property and equipment	(1)	—
Net cash used in investing activities	(1)	—
Financing activities		
Proceeds from exercise of stock options	2	2
Proceeds from issuance of Series B convertible preferred shares	6,842	—
Proceeds from Bridge Loan Notes - related parties	1,600	2,500
Net cash provided by financing activities	8,444	2,502
Increase (decrease) in cash and cash equivalents	$ 3,506	$ (2,387)
Cash and cash equivalents, beginning of year	240	3,746
Cash and cash equivalents, end of year	$ 3,746	$ 1,359
Supplemental disclosure for cash activities		
Cash paid for income taxes	$ 55	$ 8
Supplemental disclosure for non-cash activities		
Conversion of 2018 Bridge Loan Notes - related parties	$ 2,156	$ —
Vesting of restricted ordinary shares	$ —	$ 1

See accompanying notes

1. Organization and Summary of Significant Accounting Policies

Organization and Business

Oppilan Pharma, Ltd. (the “Company” or “Oppilan Pharma”), is a clinical-stage biopharmaceutical company focused on developing novel small molecule therapeutics for the treatment of autoimmune diseases. On November 3, 2016, the Company established Oppilan Pharma, Inc., a wholly owned subsidiary. The work carried out since the inception of the company solely involves the research and development of small molecule drugs targeting the sphingosine 1 phosphate (S1P) receptor for the treatment of inflammatory bowel disease and other autoimmune disorders. The focus of the company’s work to date has involved the identification of a lead drug candidate and the development of the lead candidate through early clinical trials. Its lead drug candidate, OPL-002, is a modulator of the S1P receptor that has a unique pharmacokinetic and pharmacodynamic profile, which is believed to be safer and more effective for patients. Oppilan Pharma was registered in England and Wales in May 2015, with offices in the United Kingdom and the United States of America.

Liquidity and Capital Resources

The Company has experienced net losses since inception and, as of May 31, 2019 and 2020, had an accumulated deficit of $13.8 million and $18.9 million, respectively. From inception, the Company has devoted substantially all of its resources to organizing and staffing the Company, raising capital, identifying potential product candidates, undertaking research and preclinical studies and providing general and administrative support for the operations. The Company has funded substantially all of its operations to date with proceeds from the issuance of private placements of securities and convertible promissory notes. At May 31, 2020, the Company had cash and cash equivalents of $1.4 million. On February 28, 2021, the Company was purchased by Ventyx Biosciences, Inc.; whereby, Ventyx paid the shareholders of Oppilan Pharma in the form of equity consideration of Ventyx common stock or Series A-1 convertible preferred shares (Note 11). From the date of the acquisition Oppilan Pharma became a wholly owned subsidiary of Ventyx. Based on the Company’s current business plan, management believes that existing cash and cash equivalents of the newly formed consolidated entity will be sufficient to fund the Company’s obligations for twelve months from the issuance of these financial statements. The accompanying financial statements have been prepared assuming the Company will continue as a going concern, which contemplates the realization of assets and settlement of liabilities in the normal course of business. The financial statements do not include any adjustments for the recovery and classification of assets or the amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

In addition to the foregoing, the Company is closely monitoring the impact of the COVID-19 pandemic on its business and has taken steps designed to protect the health and safety of its employees while continuing its operations. Given the level of uncertainty regarding the duration and impact of the COVID-19 pandemic on capital markets and the United States economy, the Company is currently unable to assess the impact of the COVID-19 pandemic on its future access to capital. The Company is continuing to monitor the spread of COVID-19 and its potential impact on the Company's operations. The full extent to which the COVID-19 pandemic will impact the Company's business, results of operations, financial condition, clinical trials, and preclinical research will depend on future developments that are highly uncertain, including actions taken to contain or treat COVID-19 and their effectiveness, as well as the economic impact on national and international markets.

Support Services Agreement with Kalika Biosciences, Inc.

In January 2019, the Company entered into a Support Services Agreement (the Support Services Agreement) with Kalika Biosciences, Inc. (“Kalika”), pursuant to which Kalika provides general administrative services, facilities support services, in addition to providing supplies and equipment and office space. The Support Services Agreement outlines the terms of the services provided by Kalika, as well as the fees and expenses charged for such services (Note 5). In February 2021, in conjunction with the acquisition of the Company by Ventyx Biosciences, Inc. (“Ventyx”) (Note 11), the Company terminated its agreement with Kalika.

Basis of Presentation

The accompanying consolidated financial statements have been prepared in accordance with GAAP, and include the financial statements of the Company and Oppilan Pharma, Inc. All intercompany accounts and transactions have been eliminated.

Use of Estimates

The preparation of the Company's consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that impact the reported amounts of assets, liabilities, and expenses and the disclosure of contingent assets and liabilities in the Company's consolidated financial statements and accompanying notes. On an ongoing basis, the Company evaluates its estimates and judgments, which are based on historical and anticipated results and trends and on various other assumptions that management believes to be reasonable under the circumstances. The most significant estimates in the Company's financial statements relate to estimates of accruals for research and development expenses, fair value measurements, valuation of embedded derivatives and the fair value of debt. Although these estimates are based on the Company's knowledge of current events and actions it may undertake in the future, actual results may ultimately materially differ from these estimates and assumptions.

Management believes that the following critical accounting policies are most important to understanding and evaluating the Company's reported financial results.

Foreign Currency and Currency Translation

Transactions that are denominated in a foreign currency are remeasured into the functional currency at the current exchange rate on the date of the transaction. Any foreign currency-denominated monetary assets and liabilities are subsequently remeasured at current exchange rates, with gains or losses recognized as foreign exchange gains (losses) in the consolidated statements of operations and comprehensive loss.

Cash, Cash Equivalents

Cash and cash equivalents include cash readily available in checking, savings, money market and sweep accounts. The Company considers all highly liquid investments with an original maturity of three months or less at the date of purchase to be cash equivalents.

Prepaid Expenses and Other Assets

Prepaid expenses and other assets are primarily comprised of prepayments to vendors for preclinical development costs. These costs are amortized to expense as services are performed.

Fair Value Measurements

The Company's consolidated financial instruments primarily consist of cash and cash equivalents, prepaid expenses, accounts payable and accrued liabilities. The carrying value of these financial instruments are generally considered to be representative of their respective fair values because of the short-term nature of those instruments.

The accounting guidance defines fair value, establishes a consistent framework for measuring fair value and expands disclosure for each major asset and liability category measured at fair value on either a recurring or nonrecurring basis. Fair value is defined as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability.

As a basis for considering such assumptions, the accounting guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1: Observable inputs such as quoted prices in active markets;

Level 2: Inputs, other than the quoted prices in active markets, that are observable either directly or indirectly; and

Level 3: Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

When quoted market prices are available in active markets, the fair value of assets and liabilities is estimated within Level 1 of the valuation hierarchy. If quoted prices are not available, then fair values are estimated by using pricing models, quoted prices of assets and liabilities with similar characteristics, or discounted cash flows, within Level 2 of the valuation hierarchy. In cases where Level 1 or Level 2 inputs are not available, the fair values are estimated by using inputs within Level 3 of the hierarchy. The fair value of short-term investments is based upon market prices quoted on the last day of the fiscal period or other observable market inputs. As of May 31, 2020, the Company had 2020 Bridge Loan Notes (Level 3) with related parties measured at fair value on a recurring basis.

As permitted under ASC 815-15, *Derivatives and Hedging*, entities can voluntarily choose to measure certain financial assets and liabilities at fair value ("fair value election"). The fair value election may be elected on an instrument-by-instrument basis and is irrevocable, unless a new election date occurs. If the fair value election is applied for an instrument, unrealized gains and losses for that instrument should be reported in earnings at each subsequent reporting date. As a result of applying the fair value election, direct costs and fees related to the 2020 Bridge Loan Notes were recognized as incurred and not deferred. The Company classifies the interest that has been accrued in the change in fair value of the 2020 Bridge Loan Notes on the consolidated statements of operations and comprehensive loss.

Fair value measurements associated with the Company's 2020 Bridge Loan Notes represent Level 3 instruments under the fair value hierarchy. The Company elected to account for the 2020 Bridge Loan Notes at fair value, as of the issuance date, because management believes that the fair value election better reflects the underlying economics of the 2020 Bridge Loan Notes, which contain multiple embedded derivatives. Under the fair value election, changes in fair value are reported as "Change in fair value of 2020 Bridge Loan Notes" in the consolidated statements of operations and comprehensive loss for each reporting period subsequent to issuance. The Company measured the fair value of the 2020 Bridge Loan Notes based on the inputs such as probability of a qualified financing, estimated fair value of ordinary share price the notes will be converted into, discount yield, and expected term.

The following table summarizes the Company's liabilities measured at fair value on a recurring basis as of May 31, 2020, (in thousands): The Company did not have any liabilities measured at fair value as of May 31, 2019.

	MAY 31, 2020			
	LEVEL 1	LEVEL 2	LEVEL 3	TOTAL
Liabilities:				
2020 Bridge Loan Notes	$ —	$ —	$ 2,307	$ 2,307
	$ —	$ —	$ 2,307	$ 2,307

The following table provides reconciliation for all liabilities measured at fair value using significant unobservable inputs (Level 3) for the year ended May 31, 2020 (in thousands):

Initial fair value of 2020 Bridge Loan Notes at issuance	2,500
Change in fair value of 2020 Bridge Loan Notes	(193)
Balance at May 31, 2020	**2,307**

Concentration of Credit Risk

Financial instruments, which potentially subject the Company to a concentration of credit risk, consist primarily of cash and cash equivalents. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits. The Company has not experienced any losses in such accounts and management believes that the Company is not exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held.

Property and Equipment

Property and equipment, net, which consists primarily of computer, software, and furniture and fixtures, are stated at cost less accumulated depreciation. Depreciation is calculated using the straight-line method over the estimated useful lives of the assets (generally three to seven years). Repairs and maintenance costs are charged to expense as incurred.

Long-Lived Assets

The Company reviews long-lived assets for impairment whenever events or changes in circumstances indicate the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to the future undiscounted net cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured as the amount by which the carrying amount of the assets exceeds the fair value of the assets. Fair value would be assessed using discounted cash flows or other appropriate measures of fair value. The Company did not recognize any impairment losses for the years ended May 31, 2019 and 2020.

Convertible Preferred Shares

The Company's Series A and Series B convertible preferred shares (collectively, the "convertible preferred shares") have been classified as temporary equity in the consolidated balance sheets in accordance with the authoritative guidance for the classification and measurement of potentially redeemable securities whose redemption is based upon certain change of control events outside the Company's control, including the sale or transfer of the Company. The Company records all convertible preferred shares upon issuance at their respective fair value. The Company has determined not to adjust the carrying values of the convertible preferred shares to the liquidation preferences of such shares because the occurrence of any such deemed liquidation event is not probable.

Research and Development Expenses

The Company's research and development costs consist primarily of salaries, payroll taxes, employee benefits, and stock-based compensation charges for those individuals involved in ongoing research and development efforts; as well as fees paid to consultants, contract research organizations, laboratory supplies, and development compound materials. All research and development costs are charged to expense as incurred.

Clinical Trial Accounting

The Company makes payments in connection with its clinical trials under contracts with contract research organizations that support conducting and managing clinical trials. The financial terms of these agreements are subject to negotiation and vary from contract to contract and may result in uneven payment flows. Generally, these agreements set forth the scope of work to be performed at a fixed fee, unit price or on a time and materials basis. A portion of the Company's obligation to make payments under these contracts depends on factors such as the successful enrollment or treatment of patients or the completion of other clinical trial milestones.

Expenses related to clinical trials are accrued based on estimates and/or representations from service providers regarding work performed, including actual level of patient enrollment, completion of patient studies and progress of the clinical trials. Other incidental costs related to patient enrollment or treatment are accrued when reasonably certain. If the amounts the Company is obligated to pay under clinical trial agreements are modified (for instance, as a result of changes in the clinical trial protocol or scope of work to be performed), the Company adjusts the accruals accordingly. Revisions to the contractual payment obligations are charged to expense in the period in which the facts that give rise to the revision become reasonably certain.

Patent Costs

Costs related to filing and pursuing patent applications are recorded as general and administrative expenses within the Company's consolidated statements of operations and comprehensive loss and expensed as incurred since recoverability of such expenditures is uncertain.

Stock-Based Compensation

The Company accounts for stock-based compensation expense related to employee stock options and restricted stock by estimating the fair value on the date of grant. The Company estimates the fair value of these awards to employees and non-employees using the Black-Scholes option pricing model, which requires the input of highly subjective assumptions, including (a) the risk-free interest rate, (b) the expected volatility of the

Company's shares, (c) the expected term of the award, and (d) the expected dividend yield. Due to the lack of an adequate history of a public market for the trading of the Company's common, the Company has based its estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded. For these analyses, the Company has selected companies with comparable characteristics, including enterprise value, risk profiles, and position within the industry, and with historical share price information sufficient to meet the expected life of the stock-based awards.

The Company has estimated the expected life of its employee stock options using the "simplified" method, whereby the expected life equals the average of the vesting term and the original contractual term of the option. The risk-free interest rates for periods within the expected life of the option are based on the yields of zero-coupon U.S. treasury securities. Under the fair value recognition provisions of the authoritative guidance for stock-based compensation awards, the Company measures the fair value of restricted stock and stock options at the grant date, and the fair value is recognized as expense on a straight-line basis over the requisite service period or contractual term. Forfeitures are recognized as incurred.

Income Taxes

The Company accounts for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements. Under this method, deferred tax assets and liabilities are determined on the basis of the differences between the financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized as income or expense in the period that includes the enactment date.

The Company recognizes net deferred tax assets to the extent that the Company believes these assets are more likely than not to be realized. In making such a determination, management considers all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax-planning strategies and results of recent operations. If management determines that the Company would be able to realize its deferred tax assets in the future in excess of their net recorded amount, management would make an adjustment to the deferred tax asset valuation allowance, which would reduce the provision for income taxes.

The Company records uncertain tax positions on the basis of a two-step process whereby (1) management determines whether it is more likely than not that the tax positions will be sustained on the basis of the technical merits of the position and (2) for those tax positions that meet the more-likely-than-not recognition threshold, management recognizes the largest amount of tax benefit that is more than 50% likely to be realized upon ultimate settlement with the related tax authority. The Company recognizes interest and penalties related to unrecognized tax benefits within income tax expense. Any accrued interest and penalties are included within the related tax liability.

Comprehensive Income (Loss)

Comprehensive income (loss) is defined as a change in equity during a period from transactions and other events and circumstances from non-owner sources. The only component of other comprehensive income is foreign currency translation. Comprehensive gains and losses have been reflected in the consolidated statements of operations and comprehensive loss and as a separate component in the consolidated statements of convertible preferred shares and shareholders' deficit.

Recently Adopted Accounting Pronouncements

During 2016, the FASB issued ASU No. 2016-01, *Recognition and Measurement of Financial Assets and Financial Liabilities* ("ASU No. 2016-01") which eliminates the requirement for companies to disclose the fair value of financial instruments measured at amortized cost on the balance sheet. Furthermore, the standard requires presentation of assets and liabilities separately, by measurement category and form of financial asset on the balance sheet or accompanying notes to the financial statements. The updated guidance is effective for annual periods beginning after December 15, 2018, and early adoption is permitted. The Company adopted this standard on June 1, 2019, which did not have a material impact on its consolidated financial statements and accompanying notes.

In August 2016, the FASB issued ASU No. 2016-15, *Statement of Cash Flows: Classification of Certain Cash Receipts and Cash Payments* ("ASU 2016-15") which includes amendments that clarify how certain cash receipts and cash payments are presented in the statement of cash flows. The new guidance also clarifies when an entity should separate cash receipts and cash payments and classify them into more than one class of cash flows. ASU 2016-15 is effective for nonpublic entities for annual periods beginning after December 15, 2018. Early adoption is permitted provided that all amendments are adopted in the same period. The Company adopted this standard on June 1, 2019, which did not have a material impact on its consolidated financial statements and accompanying notes.

In November 2017, the FASB issued ASU No. 2016-18, *Statement of Cash Flows (Topic 230) Restricted Cash* ("ASU 2016-18"). The new standard requires that the statement of cash flows explain the change during the period in the total of cash, cash equivalents and amounts described as restricted cash or restricted cash and equivalents. ASU 2016-18 is effective for fiscal years beginning after December 31, 2018, with early adoption permitted. The Company adopted this standard on June 1, 2019, which did not have a material impact on its consolidated financial statements and accompanying notes.

In August 2018, the FASB issued ASU No. 2018-13, *Changes to the Disclosure Requirements for Fair Value Measurement* ("ASU 2018-13"), which modifies certain disclosure requirements on fair value measurements. ASU 2018-13 is effective for interim and annual periods beginning after December 15, 2019, and early adoption is permitted. The Company adopted this standard on June 1, 2019. The Company has evaluated the effect that the updated standard had on its internal processes, financial statements and related disclosures, and has determined that the adoption did not have a material impact on the Company's historical financial statements.

Recent Accounting Pronouncements – Not Yet Adopted

In February 2016, the FASB issued ASU No. 2016-02, *Leases* ("ASU 2016-02"). The new standard establishes a right-of-use model and requires a lessee to recognize on the balance sheet a right-of-use asset and corresponding lease liability for all leases with terms longer than 12 months. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. ASU 2016-02 is effective for annual periods beginning after December 15, 2021 and early adoption is permitted. The Company is currently evaluating the impact that the adoption of this guidance will have on its consolidated financial statements and accompanying notes.

In August 2018, the FASB issued ASU 2018-13, *Changes to the Disclosure Requirements for Fair Value Measurement* ("ASU 2018-13"), which modifies certain disclosure requirements on fair value measurements. ASU 2018-13 is effective for interim and annual periods beginning after December 15, 2019, and early adoption is permitted. The Company is currently evaluating the impact the adoption of this guidance will have on its consolidated financial statements and accompanying notes.

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments–Credit Losses: Measurement of Credit Losses on Financial Instruments* ("ASU 2016-13") which amends the impairment model by requiring entities to use a forward-looking approach based on expected losses to estimate credit losses on certain types of financial instruments, including trade receivables and available-for-sale debt securities. ASU 2016-13 is effective for annual periods beginning after December 15, 2019, with early adoption permitted. The Company is currently evaluating the impact the adoption of this guidance will have on its consolidated financial statements and accompanying notes.

2. Property and Equipment

Property and equipment, net, consist of the following (in thousands):

	MAY 31,	
	2019	2020
Computers and software	$ 9	$ 9
Furniture and fixtures	23	23
	32	32
Less: Accumulated depreciation	(14)	(19)
Total property and equipment, net	$ 18	$ 13

3. Prepaid Expenses and Other Assets

Prepaid expenses and other assets consist of the following (in thousands):

	MAY 31,	
	2019	2020
Prepaid research and development	$ 490	$ 159
VAT receivable	3	4
Prepaid expenses - other	41	43
Prepaid related party	216	8
Total prepaid expenses and other assets	$ 750	$ 214

4. Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	MAY 31,	
	2019	2020
Accrued professional fees	$ 31	$ 59
Accrued research and development costs	237	437
Accrued related party liabilities	—	9
Total accrued liabilities	$ 268	$ 505

5. Other Related Party Transactions

In January 2019, the Company entered into a Support Services Agreement with Kalika Biosciences, Inc. that outlines the terms of services provided by Kalika to the Company, as well as the fees charged for such services. Kalika is a shared service company that provides certain back-office and administrative and research and development support services, including facilities support, to the portfolio companies of New Sciences Ventures, LLC. Kalika is owned by Raju Mohan, PhD., a Director of the Company, and New Science Ventures, LLC, a shareholder of the Company. The Company pays Kalika monthly for costs incurred under the agreement. Either party may terminate the support services agreement by giving 30 days' prior notice. The support services agreement automatically renews in January of each year unless terminated by either party by giving 30 days' prior notice. In February 2021, in conjunction with the acquisition of the Company by Ventyx Biosciences, Inc. ("Ventyx") (Note 11), the Company terminated its agreement with Kalika.

Related party expense recognized by the Company under the Kalika Support Services Agreement was as follows (in thousands):

	MAY 31,	
	2019	2020
Research and development	$ 146	$ 389
General and administrative	257	903
Total	$ 403	$ 1,292

At May 31, 2019 and 2020, the Company had prepaid expenses from related parties of $215,984 and $7,743, respectively. At May 31, 2019 and 2020, the Company had accounts payable and accrued expenses due to related parties of $95,633 and $122,733, respectively.

6. Debt

Series Seed Convertible Notes

Between March 2015 and November 2016, the Company issued convertible loan notes, providing the Company with $1.25 million in aggregate gross proceeds (the “Series Seed Convertible Notes”). In December 2016, $500,000 of the Series Seed Convertible Notes converted into 5,250,000 Series A Convertible Preferred Shares and $750,000 of the Series Seed Convertible Notes converted into 7,500,000 Series B Convertible Preferred Shares (Note 7).

2018 Bridge Loan Notes – Related Parties

In May 2018 and July 2018, the Company issued convertible loan notes, providing the Company with $0.5 million and $1.6 million, respectively, in aggregate gross proceeds (the “2018 Bridge Loan Notes”). The 2018 Bridge Loan Notes and accrued interest of $56,336 converted into 2,156,336 Series B Convertible Preferred Shares in December 2018 (Note 7).

2020 Bridge Loan Notes – Related Parties

In March 2020, the Company issued $2.5 million of convertible promissory notes (the “2020 Bridge Loan Notes”), to investors, with maturity dates of 12 months from the dates of issuance. The 2020 Bridge Loan Notes accrue interest at 6% per annum, due and payable at maturity unless otherwise converted prior to maturity. The 2020 Bridge Loan Notes are the Company’s senior, unsecured obligations and are (i) equal in right of payment with the Company’s future senior, unsecured indebtedness; (ii) senior in right of payment for the Company’s future indebtedness; (iii) effectively subordinated to the Company’s future secured indebtedness, to the extent of the value of the collateral securing that indebtedness; and (iv) structurally subordinated to all existing and future indebtedness and other liabilities, including trade payables.

The terms of the 2020 Bridge Loan Notes provide for the principal and accrued interest to automatically convert into the type of shares issued in a qualified financing of at least $15.0 million or, at the holder’s election, to convert into the type of shares issued in a non-qualified financing of less than $15.0 million, at a per share conversion price equal to 80% of the price paid by investors in the respective financing. Upon the occurrence of a sale of the Company, each holder may elect to redeem the 2020 Bridge Loan Notes at a price equal to 2.0 multiplied by the outstanding principal plus accrued and unpaid interest, or in lieu of the premium, to the convert the principal and accrued interest into Series B Convertible Preferred Shares. Notwithstanding the foregoing, the 2020 Bridge Loan Notes are not redeemable by the Company prior to maturity without explicit consent of the holder.

The Company elected to account for the notes and all their embedded features under the fair value election pursuant to ASC 815-15, *Derivatives and Hedging*. For the year ended May 31, 2020, the Company recognized $0.2 million of change in fair value of the 2020 Bridge Loan Notes in the consolidated statements of operations and comprehensive loss related to the decrease in the fair value of the 2020 Bridge Loan Notes. As of May 31, 2020, the fair value of the 2020 Bridge Loan Notes was $2.3 million.

7. Convertible Preferred Shares

Series A Convertible Preferred Shares

In December 2016, the Company completed its Series A Convertible Preferred Shares financing, converting $500,000 of the Series Seed Convertible Notes (Note 6) into 5,250,000 Series A Convertible Preferred Shares (the “Series A Preferred Stock”).

Series B Convertible Preferred Shares

From December 2016 to April 2017, the Company issued 7,500,000 Series B Convertible Preferred Shares at $1.00 per share (the “Series B Convertible Preferred Shares”) for aggregate proceeds of $6.65 million, net of $99,316 of issuance costs, and the conversion of $750,000 of the Series Seed Convertible Notes (Note 6).

In December 2018, the Company issued 1,843,664 Series B Convertible Preferred Shares at $1.00 per share, providing the Company with proceeds of $1,843,664 and converted $2.1 million of the 2018 Bridge Loan Notes (Note 6) plus $56,336 accrued interest into 2,156,336 Series B Convertible Preferred Shares at $1.00 per share.

In April 2019, the Company completed an additional round of its Series B Convertible Preferred Shares financing, providing the Company with proceeds of $4,998,411, net of $1,589 of issuance costs, from the issuance of 5,000,000 Series B Convertible Preferred Shares at $1.00 per share.

Dividends

The holders of the Series A and Series B Convertible Preferred Shares are entitled to participate in a dividend in proportion to the number of shares held (pari passu with the holders of equity shares). Convertible preferred share dividends are payable when and if declared by the Company's Board of Directors. As of May 31, 2020, and 2019, the Company's Board of Directors has not declared any dividends on the convertible preferred shares outstanding.

Liquidation

The holders of the Series A and Series B Convertible Preferred Shares are entitled to receive liquidation preferences at the rate of $0.095 and $1.00 per share, respectively. Liquidation payments to the holders of Series A and Series B Convertible Preferred Shares shall be distributed in priority to payment to any other share class.

Conversion

Each Series A and Series B Convertible Preferred Share is convertible at any time at the option of the holder into a number of ordinary shares determined by dividing the original issue price for such series by the applicable conversion price for such series, which conversion price is subject to adjustment under certain conditions. All outstanding convertible preferred shares will be automatically converted upon the closing of firm commitment underwritten public offering.

Voting Rights

The holders of the Series A and Series B Convertible Preferred Shares are entitled to vote together with the holders of ordinary shares on all matters submitted to shareholders for a vote. Each holder of convertible preferred shares is entitled to the number of votes equal to the number of ordinary shares into which such convertible preferred shares could be converted at the record date for determination of the shareholders entitled to vote.

8. Shareholders’ Equity

Ordinary Shares

The Company is authorized to issue 4,513,752 and 4,526,158 shares each having a nominal value of $0.001 at May 31, 2019 and 2020, respectively. All of the existing issued ordinary shares are fully paid. Accordingly, no further capital may be required by the Company from the holders of such shares. The rights and restrictions to which the ordinary shares will be subject are prescribed in the Articles of Association. The Articles of Association permit the board of directors, with shareholder approval, to determine the terms of any preferred shares that may be issued. The board of directors is authorized, having obtained the consent of the shareholders, to provide from time to time the issuance of other classes or series of shares and to establish the characteristics of each class or series, including the number of shares, designations, relative voting rights,

dividend rights, liquidation and other rights, redemption, repurchase or exchange rights and any other preferences and relative, participating, optional or other rights and limitations not inconsistent with applicable law.

Ordinary shares reserved for future issuance consists of the following at May 31, 2020:

Conversion of Preferred Stock	21,750,000
Stock options issued and outstanding	872,833
Authorized for future option grants	142,467
	22,765,300

9. Equity Incentive Plan

In December 2016, the Company adopted its 2016 Equity Incentive Plan (the Plan). The Plan provides for the grant of incentive stock options and non-statutory stock options to employees, directors or consultants of the Company. Options granted under the Plan generally vest over a period of 3 years, as determined by the Board of Directors, and the maximum term of stock options granted under the Plan is 10 years. As of May 31, 2019 and 2020, the Company had 1,046,317 shares authorized for issuance under the Plan and 776,484 and 142,467 shares, respectively, remained available for grant.

Stock Options

The following table summarizes stock option activity during the year ended May 31, 2020:

	NUMBER OF OPTIONS	WEIGHTED AVERAGE EXERCISE PRICE	WEIGHTED AVERAGE REMAINING CONTRACT LIFE IN YEARS	TOTAL AGGREGATE INTRINSIC VALUE (IN THOUSANDS)
Outstanding at May 31, 2019	251,222	$ 0.13	7.9	—
Granted	715,500	0.28		
Exercised	(12,406)	(0.13)		
Cancelled / Forfeited	(81,483)	(0.13)		
Outstanding at May 31, 2020	872,833	$ 0.25	9.0	32
Vested and expected to vest at May 31, 2020	504,222	$ 0.28	9.8	32
Exercisable at May 31, 2020	368,611	$ 0.19	8.1	32

The intrinsic value of a stock option is the difference between the market price of the ordinary shares at measurement date and the exercise price of the option. The weighted average grant date fair value of stock options granted during the years ended May 31, 2019 and 2020 was $0.09 and $0.19, respectively, for employees and nonemployees.

As of May 31, 2019 and 2020, total unrecognized stock-based compensation costs related to unvested employee stock options was $144,676 and $122,885, respectively, and is expected to be recognized over the weighted average period of approximately 3.2 and 2.4 years, respectively, on a straight-line basis. The Company recorded stock-based compensation expense of $64,004 and $32,596 for the years ended May 31, 2019 and 2020, respectively.

The following table shows the weighted average assumptions used to compute the fair value of the awards granted to employees and nonemployees, using the Black-Scholes option-pricing model.

	MAY 31,	
ASSUMPTION	**2019**	**2020**
Expected volatility	80.00%	80.00%
Expected term (years)	5.78	5.78
Expected dividend yield	0.00%	0.00%
Risk-free interest rate	2.28%	1.94%

The risk-free interest rate assumption was based on the United States Treasury's rates for U.S. Treasury zero-coupon bonds with maturities similar to those of the expected term of the award being valued. The assumed dividend yield was based on the Company's expectation of not paying dividends in the foreseeable future. For awards granted to nonemployees, the full remaining contractual term is used. The estimated volatility reflects an average volatility of comparable companies whose share prices are publicly available adjusted to align with the stage of development the Company is currently at.

Restricted Ordinary Shares

In 2016, the Company issued 4,537,017 restricted ordinary shares with a weighted average grant date fair value of $0.13 per share to various employees, advisors and directors of the Company, which vest over a period of zero to three years. Upon the termination of service of a restricted shareholder, the Company has the option to repurchase any unvested shares. During the years ended May 31, 2019 and 2020, the Company repurchased 41,875 and 0 shares, respectively.

The Company has recorded an immaterial amount of liability for the years ended May 31, 2019 and 2020 related to the unvested restricted ordinary shares subject to repurchase. The Company reduces the liability as the underlying shares vest. At May 31, 2019 and 2020, 83,750 and 0 shares, respectively, subject to repurchase remained unvested.

	NUMBER OF RESTRICTED ORDINARY SHARES		**WEIGHTED AVERAGE GRANT DATE FAIR VALUE**
Balance at May 31, 2019	83,750	$	10,888
Vested	(83,750)	$	(10,888)
Canceled / Forfeited	—		—
Balance at May 31, 2020	**—**	$	—

10. Income Taxes

A reconciliation of income tax provision to amounts computed by applying the United Kingdom (U.K.) statutory income tax rate to loss from continuing operations before income taxes is shown as follows (in thousands):

	MAY 31,	
	2019	**2020**
Statutory federal income tax rate	19.0%	19.0%
Attribute adjustment for research and development credit	0.0%	(20.6)%
Valuation allowance	(18.3)%	1.4%
Other	(0.7)%	0.2%
Effective income tax rate	0.0%	0.0%

The Company's deferred tax assets as of May 31, 2019 and 2020 are summarized below (in thousands):

	MAY 31,	
	2019	2020
Pre-trading expenditures	$ 2,513	$ 2,433
Other	12	19
Valuation allowance	(2,525)	(2,452)
Total deferred tax balances	$ —	$ —

For the year ended May 31, 2019 and May 31, 2020 the Company had U.K. pre-trading expenditures of approximately $13.2 million and $12.8 million, respectively. All expenditures were incurred after May 2015. Tax relief for pre-trading expenditures is generally limited to the expenditures incurred in the seven years prior to trade commencing.

Due to the Company’s history of losses and uncertainty regarding future earnings, a valuation allowance has been recorded against the Company's deferred tax assets, as it is not more likely than not that such assets will be realized.

The Company recognizes a tax benefit from an uncertain tax position when it is more likely than not that the position will be sustained. The Company had no accrual for uncertain tax positions or interest and penalties on uncertain tax positions for the years ended May 31, 2019 and 2020. The Company records interest and penalties as a component of income tax expense, if applicable.

U.K. tax authorities may raise an inquiry into a submitted return within two years from the end of the tax year. The Company has not been, nor is it currently, under examination by any income tax authority. The inquiry window for the company’s 2019 and 2020 U.K. tax returns closes on May 31, 2021 and 2022, respectively.

U.K.’s Research and Development Tax Relief Scheme

The Company conducts research and development (R&D) activities that benefit from U.K.’s small and medium-sized enterprises (SMEs) R&D tax relief scheme. Under this tax relief scheme, a SME can make an election to receive an enhanced U.K. tax deduction for its qualifying expenditure on its eligible R&D activities. As the tax incentives may be received without regard to an entity’s actual tax liability, they are not subject to accounting for income taxes. Amounts recognized by the Company for cash payment claims under the SME R&D tax relief scheme are recorded as a reduction of R&D expenses as received, following the submission of the claim and the determination that collectability is deemed probable and reasonably assured.

In May 2020, the Company adjusted the gross deferred tax asset for pre-trading losses by submitting claims to receive cash payments of $0.8 million and $1.0 million related to tax years ending May 31, 2018 and 2019, respectively.

In July 2020 and November 2020 the Company received $1.8 million and $0.9 million, respectively, upon approval of the Company’s submitted claim by the U.K. tax authorities.

11. Subsequent Events

The Company has evaluated subsequent events from the balance sheet date through August 20, 2021, the date at which the consolidated financial statements were available to be issued. Aside from the events disclosed below, the Company has determined that there are no other items to disclose.

Ventyx Biosciences, Inc. Accounting Acquirer

On February 26, 2021, Ventyx Biosciences, Inc. (“Ventyx”), a clinical-stage pharmaceutical company incorporated in the State of Delaware, acquired 100% of the then-outstanding ordinary and preferred shares of the Company and Zomagen Biosciences Ltd. (“Zomagen”). Pursuant to the terms of the Share Purchase Agreement (the “Agreement”), upon closing, Ventyx paid the shareholders of the Company in the form of equity consideration of 42,905,591 shares of Ventyx common stock, stock options and Series A-1 convertible preferred stock, which includes 5,143,425 shares of Ventyx’s Series A-1 convertible preferred stock, issued upon the conversion of the 2020 Bridge Loan Notes.

OPPILAN PHARMA, LTD

Consolidated Balance Sheets
(in thousands except share and nominal value amounts)

	MAY 31, 2020	NOVEMBER 30, 2020 (UNAUDITED)
Assets		
Current assets:		
Cash and cash equivalents	1,359	2,630
Prepaid expenses and other assets (includes related party amounts of $8 and $31, respectively)	214	87
Total current assets	1,573	2,717
Property and equipment, net	13	11
Other long-term assets	—	—
Total assets	1,586	$ 2,728
Liabilities, convertible preferred shares and shareholder' deficit		
Current liabilities:		
Accounts payable (includes related party amounts of $114 and $101, respectively)	$ 141	199
Accrued expenses (includes related party amounts of$9 and $0, respectively)	505	919
2020 Bridge Loan Notes at fair value - related parties	2,307	1,860
Total current liabilities	2,953	2,978
Total liabilities	2,953	2,978
Commitments and contingencies		
Convertible preferred shares		
Series A convertible preferred shares, $0.001 nominal value; 5,250,000 shares authorized, issued and outstanding at May 31, 2020 and November 30, 2020 (unaudited), respectively; liquidation preference of $498 at May 31, 2020 and November 30, 2020 (unaudited), respectively	500	500
Series B convertible preferred shares, $0.001 nominal value; 19,150,000 shares authorized at May 31, 2020 and November 30, 2020 (unaudited), respectively; 16,500,000 shares issued and outstanding at May 31, 2020 and November 30, 2020 (unaudited), respectively; liquidation preference of $16,500 at May 31, 2020 and November 30, 2020 (unaudited), respectively	16,391	16,391
Shareholders' deficit		
Share Capital, $0.001 nominal value; 4,513,752 and 4,526,158 ordinary shares authorized and issued at May 31, 2020 and November 30, 2020, respectively; 4,430,002 and 4,526,1558 outstanding at May 31, 2020 and November 30, 2020, respectively	5	5
Additional paid-in capital	623	650
Accumulated other comprehensive (loss) income	4	(30)
Accumulated deficit	(18,890)	(17,766)
Total shareholders’ deficit	(18,258)	(17,141)
Total liabilities, convertible preferred shares and shareholders' deficit	1,586	$ 2,728

See accompanying notes

OPPILAN PHARMA, LTD

Consolidated Statements of Operations and Comprehensive Income (Loss)
(in thousands)
(unaudited)

	SIX MONTHS ENDED NOVEMBER 30,	
	2019	**2020**
Operating expenses:		
Research and development (includes related party amounts of $203 and $156, respectively)	$ 2,847	$ 1,468
Research and development - United Kingdom Tax Credits	—	(2,776)
General and administrative (includes related party amounts of $344 and $406, respectively)	495	631
Total operating (income) expenses	3,342	(677)
Income (loss) from operations	(3,342)	677
Other income (expense):		
Interest expense	—	—
Other income (expense)	(8)	—
Change in fair value of 2020 Bridge Loan Notes - related parties	—	447
Net (loss) income	(3,350)	1,124
Other comprehensive (loss) income		
Foreign currency translation	—	(34)
Comprehensive (loss) income	$ (3,350)	$ 1,090

See accompanying notes

OPPILAN PHARMA, LTD

Consolidated Statements of Convertible Preferred Shares and Shareholders' Deficit
(in thousands, except share amounts)
(unaudited)

	SIX MONTHS ENDED NOVEMBER 30, 2020									
	SERIES A CONVERTIBLE PREFERRED SHARES		SERIES B CONVERTIBLE PREFERRED SHARES		ORDINARY SHARES		ADDITIONAL PAID-IN CAPITAL	ACCUMULATLED OTHER COMPREHENSIVE INCOME (LOSS)	ACCUMULATED DEFICIT	'TOTAL SHAREHOLDERS' DEFICIT
	SHARES	AMOUNT	SHARES	AMOUNT	SHARES	AMOUNT				
Balance at May 31, 2020	5,250,000	$ 500	16,500,000	$ 16,391	4,526,158	$ 5	$ 623	$ 4	$ (18,890)	$ (18,258)
Stock-based compensation							27		—	27
Foreign currency translation							—	(34)	—	(34)
Net income									1,124	1,124
Balance at November 30, 2020	5,250,000	$ 500	16,500,000	$ 16,391	4,526,158	$ 5	$ 650	$ (30)	$ (17,766)	$ (17,141)

	SIX MONTHS ENDED NOVEMBER 30, 2019									
	SERIES A CONVERTIBLE PREFERRED SHARES		SERIES B CONVERTIBLE PREFERRED SHARES		ORDINARY SHARES		ADDITIONAL PAID-IN CAPITAL	ACCUMULATLED OTHER COMPREHENSIVE INCOME (LOSS)	ACCUMULATED DEFICIT	'TOTAL SHAREHOLDERS' DEFICIT
	SHARES	AMOUNT	SHARES	AMOUNT	SHARES	AMOUNT				
Balance at May 31, 2019	—	$ 500	—	$ 16,391	—	$ —	588	4	$ (13,753)	$ (13,161)
Net loss									(3,350)	(3,350)
Balance at November 30, 2019	—	$ 500	—	$ 16,391	—	$ —	$ 588	$ 4	$ (17,103)	$ (16,511)

See accompanying notes

OPPILAN PHARMA, LTD

Consolidated Statements of Cash Flows
(in thousands)
(unaudited)

	SIX MONTHS ENDED NOVEMBER 30,	
	2019	2020
Net (loss) income	$ (3,350)	$ 1,124
Operating activities		
Adjustments to reconcile net (loss) income to net cash (used in) provided by operating activities:		
Depreciation	4	2
Interest expense	—	75
Stock-based compensation	—	27
Foreign exchange (gain) on operating cash flows	—	(34)
Change in fair value of 2020 Bridge Loan Notes	—	(522)
Changes in operating assets and liabilities:		
Prepaid expenses and other assets (includes related party amounts of $193 and ($23), respectively)	458	127
Accounts payable	(171)	70
Accrued expenses (includes related party amounts of $18 and ($22), respectively)	395	402
Net cash (used in) provided by operating activities	(2,664)	1,271
Increase (decrease) in cash and cash equivalents	$ (2,664)	$ 1,271
Cash and cash equivalents, beginning of period	3,746	1,359
Cash and cash equivalents, end of period	$ 1,082	$ 2,630
Supplemental disclosure for cash activities		
Cash paid for income taxes	$ 8	$ —

See accompanying notes

1. Organization and Summary of Significant Accounting Policies

Organization and Business

Oppilan Pharma, Ltd. (the “Company” or “Oppilan Pharma”), is a clinical-stage biopharmaceutical company focused on developing novel small molecule therapeutics for the treatment of autoimmune diseases. The company’s mission is to improve the lives of patients suffering from autoimmune diseases. The work carried out since the inception of the company solely involves the research and development of small molecule drugs targeting the sphingosine 1 phosphate (S1P) receptor for the treatment of inflammatory bowel disease and other autoimmune disorders. The focus of the company’s work to date has involved the identification of a lead drug candidate and the development of the lead candidate through early clinical trials. Its lead drug candidate, OPL-002, is a potent and selective modulator of the S1P receptor that has a unique pharmacokinetic and pharmacodynamic profile, which is believed to be safer and more effective for patients. Oppilan Pharma was registered in England and Wales in May 2015, with offices in United Kingdom and the United States of America.

Liquidity and Capital Resources

The Company has experienced net losses since inception and, as of November 30, 2020, had an accumulated deficit of $17.8 million. From inception, the Company has devoted substantially all its resources to organizing and staffing the Company, raising capital, identifying potential product candidates, undertaking research and preclinical studies and providing general and administrative support for the operations. The Company has funded substantially all its operations to date with proceeds from the issuance of private placements of securities and convertible promissory notes. At May 31, 2020 and November 30, 2020, the Company had cash and cash equivalents of $1.4 million and $2.6 million, respectively. On February 28, 2021, the Company was purchased by Ventyx Biosciences, Inc. (“Ventyx”); whereby, Ventyx paid the stockholders of Oppilan Pharma in the form of equity consideration of Ventyx common stock or Series A-1 convertible preferred stock (Note 10). From the date of the acquisition Oppilan Pharma will become a wholly owned subsidiary of Ventyx. Based on the Company’s current business plan, management believes that existing cash and cash equivalents of the newly formed consolidated entity will be sufficient to fund the Company’s obligations for twelve months from the issuance of these financial statements. The accompanying financial statements have been prepared assuming the Company will continue as a going concern, which contemplates the realization of assets and settlement of liabilities in the normal course of business. The financial statements do not include any adjustments for the recovery and classification of assets or the amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

In addition to the foregoing, the Company is closely monitoring the impact of the COVID-19 pandemic on its business and has taken steps designed to protect the health and safety of its employees while continuing its operations. Given the level of uncertainty regarding the duration and impact of the COVID-19 pandemic on capital markets and the United States economy, the Company is currently unable to assess the impact of the COVID-19 pandemic on its future access to capital. The Company is continuing to monitor the spread of COVID-19 and its potential impact on the Company's operations. The full extent to which the COVID-19 pandemic will impact the Company's business, results of operations, financial condition, clinical trials, and preclinical research will depend on future developments that are highly uncertain, including actions taken to contain or treat COVID-19 and their effectiveness, as well as the economic impact on national and international markets.

Support Services Agreement with Kalika Biosciences, Inc.

In January 2019, the Company entered into a Support Services Agreement (the Support Services Agreement) with Kalika Biosciences, Inc. (Kalika), pursuant to which Kalika provides certain services to us, including general administrative services and facilities support services, and provides us with supplies and equipment, and office space. The Support Services Agreement outlines the terms of the services provided by Kalika to us, as well as the fees and expenses charged for such services. In February 2021, in conjunction with the

acquisition of the Company by Ventyx Biosciences, Inc. (“Ventyx”) (Note 10), the Company terminated its agreement with Kalika.

Basis of Presentation

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (GAAP), and include the financial statements of Oppilan Pharma, Ltd. and Oppilan Pharma, Inc. All intercompany accounts and transactions have been eliminated.

Unaudited Interim Financial Data

The accompanying consolidated financial statements are unaudited and have been prepared by the Company in accordance with GAAP, as found in the Accounting Standards Codification, or ASC, of the Financial Accounting Standards Board, or FASB. Certain information and footnote disclosures normally included in the Company’s annual financial statements have been omitted. These interim consolidated financial statements, in the opinion of management, reflect all normal recurring adjustments necessary for a fair presentation of the Company’s financial position and results of operations for the interim six-month periods ended November 30, 2019 and 2020.

Use of Estimates

The Company’s consolidated financial statements are prepared in accordance with GAAP. The preparation of the Company’s consolidated financial statements requires management to make estimates and assumptions that impact the reported amounts of assets, liabilities, and expenses and the disclosure of contingent assets and liabilities in the Company’s consolidated financial statements and accompanying notes. Although these estimates are based on the Company’s knowledge of current events and actions it may undertake in the future, actual results may ultimately materially differ from these estimates and assumptions.

Accrued Research and Development Costs

The Company records accruals for estimated research and development costs, comprising payments for work performed by third party contractors, laboratories, participating clinical trial sites and others. Some of these contractors bill monthly based on actual services performed, while others bill periodically based upon achieving certain contractual milestones. Payments made in advance of or after performance are reflected in the consolidated balance sheets as prepaid expenses or accrued liabilities, respectively. Up-front costs, such as costs associated with setting up clinical trial sites for participation in the trials, are expensed immediately once the set-up has occurred as research and development expenses. The Company accrues the costs incurred under agreements with these third parties based on estimates of actual work completed in accordance with the respective agreements. If the actual timing of the performance of services or the level of effort varies from the estimate, the Company adjusts accrued expenses or prepaid expenses accordingly, which impact research and development expenses. Although the Company does not expect its estimates to be materially different from amounts actually incurred, the Company’s understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low in any particular period. The Company has not experienced any material differences between accrued or prepaid costs and actual costs incurred since inception.

Foreign Currency and Currency Translation

Transactions that are denominated in a foreign currency are remeasured into the functional currency at the current exchange rate on the date of the transaction. Any foreign currency-denominated monetary assets and liabilities are subsequently remeasured at current exchange rates, with gains or losses recognized as foreign exchange gains (losses) in the consolidated statements of operations and comprehensive loss.

Cash, Cash Equivalents

Cash and cash equivalents include cash readily available in checking, savings, money market and sweep accounts. The Company considers all highly liquid investments with an original maturity of three months or less at the date of purchase to be cash equivalents.

Prepaid Expenses and Other Assets

Prepaid expenses and other assets are primarily comprised of prepayments to vendors for research, development and miscellaneous operating costs. These costs are amortized to expense as services are performed. Other assets are comprised of refundable VAT payments.

Fair Value Measurements

The Company's consolidated financial instruments primarily consist of cash and cash equivalents, prepaid expenses, accounts payable and accrued liabilities. The carrying value of these financial instruments are generally considered to be representative of their respective fair values because of the short-term nature of those instruments.

The accounting guidance defines fair value, establishes a consistent framework for measuring fair value and expands disclosure for each major asset and liability category measured at fair value on either a recurring or nonrecurring basis. Fair value is defined as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability.

As a basis for considering such assumptions, the accounting guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1: Observable inputs such as quoted prices in active markets;

Level 2: Inputs, other than the quoted prices in active markets, that are observable either directly or indirectly; and

Level 3: Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

When quoted market prices are available in active markets, the fair value of assets and liabilities is estimated within Level 1 of the valuation hierarchy. If quoted prices are not available, then fair values are estimated by using pricing models, quoted prices of assets and liabilities with similar characteristics, or discounted cash flows, within Level 2 of the valuation hierarchy. In cases where Level 1 or Level 2 inputs are not available, the fair values are estimated by using inputs within Level 3 of the hierarchy. The fair value of short-term investments is based upon market prices quoted on the last day of the fiscal period or other observable market inputs. As of May 31, 2020 and November 30, 2020, the Company had 2020 Bridge Loan Notes (Level 3) measured at fair value on a recurring basis.

As permitted under ASC 815-15, *Derivatives and Hedging*, entities can voluntarily choose to measure certain financial assets and liabilities at fair value ("fair value election"). The fair value election may be elected on an instrument-by-instrument basis and is irrevocable, unless a new election date occurs. If the fair value election is applied for an instrument, unrealized gains and losses for that instrument should be reported in earnings at each subsequent reporting date. As a result of applying the fair value election, direct costs and fees related to the 2020 Bridge Loan Notes were recognized as incurred and not deferred. The Company classifies the interest that has been accrued in the change in fair value of the 2020 Bridge Loan Notes on the consolidated statements of operations and comprehensive loss for both the six months ended May 31, 2020 and November 30, 2020.

Fair value measurements associated with assets and liabilities measured at fair value represent Level 3 instruments under the fair value hierarchy. The Company elected to account for the 2020 Bridge Loan Notes at fair value, as of the issuance date, because management believes that the fair value election better reflects the underlying economics of the 2020 Bridge Loan Notes, which contain multiple embedded derivatives. Under the fair value election, changes in fair value are reported as "Change in fair value of 2020 Bridge Loan Notes" in the consolidated statements of operations and comprehensive loss for each reporting period subsequent to issuance. The Company measured the fair value of the 2020 Bridge Loan Notes based on the inputs such as probability of a qualified financing , estimated fair value of ordinary share price the notes will be converted into, discount yield, and expected term, .

The following table summarizes the Company's liabilities measured at fair value on a recurring basis as of May 31, 2020 and November 30, 2020, respectively (in thousands):

	MAY 31, 2020			
	Level 1	Level 2	Level 3	Total
Liabilities:				
2020 Bridge Loan Notes	$ —	$ —	$ 2,307	$ 2,307
	$ —	$ —	$ 2,307	$ 2,307

	NOVEMBER 30, 2020			
	Level 1	Level 2	Level 3	Total
Liabilities:				
2020 Bridge Loan Notes			$ 1,860	$ 1,860
	$ —	$ —	$ 1,860	$ 1,860

The following table provides reconciliation for all liabilities measured at fair value using significant unobservable inputs (Level 3) as of May 31, 2020 and November 30, 2020 (in thousands):

Initial fair value of 2020 Bridge Loan Notes at issuance	**$ 2,500**
Change in fair value of 2020 Bridge Loan Notes	(193)
Balance at May 31, 2020	**$ 2,307**
Change in fair value of 2020 Bridge Loan Notes	(447)
Balance at November 30, 2020	**$ 1,860**

Concentration of Credit Risk

Financial instruments, which potentially subject the Company to a concentration of credit risk, consist primarily of cash and cash equivalents. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits. The Company has not experienced any losses in such accounts and management believes that the Company is not exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held.

Property and Equipment

Property and equipment, net, which consists primarily of computer, software, and furniture and fixtures, are stated at cost less accumulated depreciation. Depreciation is calculated using the straight-line method over the estimated useful lives of the assets (generally three to seven years). Repairs and maintenance costs are charged to expense as incurred.

Long-Lived Assets

The Company reviews long-lived assets for impairment whenever events or changes in circumstances indicate the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to the future undiscounted net cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured as the amount by which the carrying amount of the assets exceeds the fair value of the assets. Fair value would be assessed using discounted cash flows or other appropriate measures of fair value. The Company did not recognize any impairment losses for the year ended May 31, 2020 and the six-month period ended November 30, 2020.

Convertible Preferred Shares

The Company's Series A and Series B convertible preferred shares (collectively, the "convertible preferred shares") have been classified as temporary equity in the consolidated balance sheets in accordance with the authoritative guidance for the classification and measurement of potentially redeemable securities whose

redemption is based upon certain change of control events outside the Company's control, including the sale or transfer of the Company. The Company records all convertible preferred shares upon issuance at its respective fair value. The Company has determined not to adjust the carrying values of the convertible preferred shares to the liquidation preferences of such shares because the occurrence of any such deemed liquidation event is not probable.

Research and Development Expenses

The Company's research and development costs consist primarily of salaries, payroll taxes, employee benefits, and stock-based compensation charges for those individuals involved in ongoing research and development efforts; as well as fees paid to consultants, contract research organizations, laboratory supplies, and development compound materials. All research and development costs are charged to expense as incurred.

Clinical Trial Accounting

The Company makes payments in connection with its clinical trials under contracts with contract research organizations that support conducting and managing clinical trials. The financial terms of these agreements are subject to negotiation and vary from contract to contract and may result in uneven payment flows. Generally, these agreements set forth the scope of work to be performed at a fixed fee, unit price or on a time and materials basis. A portion of the Company's obligation to make payments under these contracts depends on factors such as the successful enrollment or treatment of patients or the completion of other clinical trial milestones.

Expenses related to clinical trials are accrued based on estimates and/or representations from service providers regarding work performed, including actual level of patient enrollment, completion of patient studies and progress of the clinical trials. Other incidental costs related to patient enrollment or treatment are accrued when reasonably certain. If the amounts the Company is obligated to pay under clinical trial agreements are modified (for instance, as a result of changes in the clinical trial protocol or scope of work to be performed), the Company adjusts the accruals accordingly. Revisions to the contractual payment obligations are charged to expense in the period in which the facts that give rise to the revision become reasonably certain.

Patent Costs

Costs related to filing and pursuing patent applications are recorded as general and administrative expenses within the Company's consolidated statements of operations and comprehensive loss and expensed as incurred since recoverability of such expenditures is uncertain.

Research and Development United Kingdom Tax Credits

The Company applies for refundable United Kingdom research and development tax credits. Tax credits are recorded within the Company's consolidated statements of operations and comprehensive loss when they are received.

Stock-Based Compensation

The Company accounts for stock-based compensation expense related to employee stock options and restricted stock by estimating the fair value on the date of grant. The Company estimates the fair value of these awards to employees and non-employees using the Black-Scholes option pricing model, which requires the input of highly subjective assumptions, including (a) the risk-free interest rate, (b) the expected volatility of the Company's shares, (c) the expected term of the award, and (d) the expected dividend yield. Due to the lack of an adequate history of a public market for the trading of the Company's ordinary shares, the Company has based its estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded. For these analyses, the Company has selected companies with comparable characteristics, including enterprise value, risk profiles, and position within the industry, and with historical share price information sufficient to meet the expected life of the stock-based awards.

The Company has estimated the expected life of its employee stock options using the "simplified" method, whereby the expected life equals the average of the vesting term and the original contractual term of the option. The risk-free interest rates for periods within the expected life of the option are based on the yields of zero-coupon U.S. treasury securities. Under the fair value recognition provisions of the authoritative guidance for stock-based compensation awards, the Company measures the fair value of restricted stock and stock options at the grant date, and the fair value is recognized as expense on a straight-line basis over the requisite service period or contractual term. Forfeitures are recognized as incurred.

Income Taxes

The Company accounts for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements. Under this method, deferred tax assets and liabilities are determined on the basis of the differences between the financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized as income or expense in the period that includes the enactment date.

The Company recognizes net deferred tax assets to the extent that the Company believes these assets are more likely than not to be realized. In making such a determination, management considers all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax-planning strategies and results of recent operations. If management determines that the Company would be able to realize its deferred tax assets in the future in excess of their net recorded amount, management would make an adjustment to the deferred tax asset valuation allowance, which would reduce the provision for income taxes.

The Company records uncertain tax positions on the basis of a two-step process whereby (1) management determines whether it is more likely than not that the tax positions will be sustained on the basis of the technical merits of the position and (2) for those tax positions that meet the more-likely-than-not recognition threshold, management recognizes the largest amount of tax benefit that is more than 50% likely to be realized upon ultimate settlement with the related tax authority. The Company recognizes interest and penalties related to unrecognized tax benefits within income tax expense. Any accrued interest and penalties are included within the related tax liability.

Comprehensive Income (Loss)

Comprehensive income (loss) is defined as a change in equity during a period from transactions and other events and circumstances from non-owner sources. The only component of other comprehensive income is foreign currency translation. Comprehensive gains and losses have been reflected in the consolidated statements of operations and comprehensive loss and as a separate component in the consolidated statements of convertible preferred shares and shareholders' deficit.

Recently Adopted Accounting Pronouncements

In August 2018, the FASB issued ASU 2018-13, *Changes to the Disclosure Requirements for Fair Value Measurement* ("ASU 2018-13"), which modifies certain disclosure requirements on fair value measurements. ASU 2018-13 is effective for interim and annual periods beginning after December 15, 2019, and early adoption is permitted. The Company is currently evaluating the impact the adoption of this guidance will have on its consolidated financial statements and accompanying notes.

Recent Accounting Pronouncements – Not Yet Adopted

In February 2016, the FASB issued ASU No. 2016-02, *Leases* ("ASU 2016-02"). The new standard establishes a right-of-use model and requires a lessee to recognize on the balance sheet a right-of-use asset and corresponding lease liability for all leases with terms longer than 12 months. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. ASU 2016-02 is effective for annual periods beginning after December 15, 2021 and early adoption is permitted. The Company is currently evaluating the impact that the adoption of this guidance will have on its consolidated financial statements and accompanying notes.

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments–Credit Losses: Measurement of Credit Losses on Financial Instruments* ("ASU 2016-13") which amends the impairment model by requiring entities to use a forward-looking approach based on expected losses to estimate credit losses on certain types of financial instruments, including trade receivables and available-for-sale debt securities. ASU 2016-13 is effective for annual periods beginning after December 15, 2019, with early adoption permitted. The Company is currently evaluating the impact the adoption of this guidance will have on its consolidated financial statements and accompanying notes.

2. Property and Equipment

Property and equipment, net, consists of the following (in thousands):

	MAY 31, 2020	NOVEMBER 30, 2020
Computers and software	$ 9	**$ 9**
Furniture and fixtures	23	**23**
	32	**32**
Less: Accumulated depreciation	(19)	**(21)**
Total property and equipment, net	$ 13	**$ 11**

3. Prepaid Expenses and Other Assets

Prepaid expenses and other assets consist of the following (in thousands):

	MAY 31, 2020	NOVEMBER 30, 2020
Prepaid research and development	$ 159	**$ 3**
VAT receivable	4	**23**
Prepaid expenses-other	43	**30**
Other assets- related parties	8	**31**
Total prepaid expenses and other assets	$ 214	**$ 87**

4. Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	MAY 31, 2020	NOVEMBER 30, 2020
Accrued professional fees	$ 59	**$ 42**
Accrued research and development costs	437	**877**
Accrued related party liabilities	9	**—**
Total accrued liabilities	$ 505	**$ 919**

5. Other Related Party Transactions

In January 2019, the Company entered into a Support Services Agreement with Kalika Biosciences, Inc. (“Kalika”) that outlines the terms of services provided by Kalika to the Company, as well as the fees charged for such services. Kalika is a shared service company that provides certain back-office and administrative and research and development support services, including facilities support, to the portfolio companies of New Sciences Ventures, LLC. Kalika is owned by Raju Mohan, PhD., a Director of the Company, and New Science Ventures, LLC, a shareholder of the Company. The Company pays Kalika monthly for costs incurred under the agreement. Either party may terminate the support services agreement by giving 30 days’ prior notice. The support services agreement automatically renews in January of each year unless terminated by either party by giving 30 days’ prior notice.

Related party expense recognized by the Company under the Kalika Support Services Agreement was as follows (in thousands):

	SIX MONTHS ENDED NOVEMBER 30,	
	2019	2020
Research and development	$ 203	**$ 156**
General and administrative	344	**406**
Total	$ 547	**$ 562**

At May 31, 2020 and November 30, 2020, the Company had prepaid expenses to Kalika or its affiliates of $7,743 and $30,880, respectively. At May 31, 2020 and November 30, 2020, the Company had accounts payable and accrued expenses due to Kalika or its affiliates of $122,733 and $101,167, respectively.

6. Debt

Series Seed Convertible Notes

Between March 2015 and November 2016, the Company issued convertible loan notes, providing the Company with $1.25 million in aggregate gross proceeds (the “Series Seed Convertible Notes”). $500,000 of the Series Seed Convertible Notes converted into 5,250,000 shares of Series A Convertible Preferred Shares and $750,000 of the Series Seed Convertible Notes converted into 7,500,000 of Series B Convertible Preferred Shares (Note 7).

2018 Bridge Loan Notes

In May and July 2018, the Company issued convertible loan notes, providing the Company with $0.5 million and $1.6 million, respectively, in aggregate gross proceeds (the “2018 Bridge Loan Notes”). The 2018 Bridge Loan Notes and accrued interest of $56,336 converted into 2,156,336 Series B Convertible Preferred Shares in December 2018 (Note 7).

2020 Bridge Loan Notes

In March 2020, the Company issued $2.5 million of convertible promissory notes (the “2020 Bridge Loan Notes”), to investors, with maturity dates of 12 months from the dates of issuance. The 2020 Bridge Loan Notes accrue interest at 6% per annum, due and payable at maturity unless otherwise converted prior to maturity. The 2020 Bridge Loan Notes are the Company’s senior, unsecured obligations and are (i) equal in right of payment with the Company’s future senior, unsecured indebtedness; (ii) senior in right of payment for the Company’s future indebtedness; (iii) effectively subordinated to the Company’s future secured indebtedness, to the extent of the value of the collateral securing that indebtedness; and (iv) structurally subordinated to all existing and future indebtedness and other liabilities, including trade payables.

The terms of the 2020 Bridge Loan Notes provide for the principal and accrued interest to automatically convert into the type of shares issued in a qualified financing of at least $15.0 million or, at the holder’s election, to convert into the type of shares issued in a non-qualified financing of less than $15.0 million, at a per share conversion price equal to 80% of the price paid by investors in the respective financing. Upon the occurrence of a sale of the Company, each holder may elect to redeem the 2020 Bridge Loan Notes at a price equal to 2.0 multiplied by the outstanding principal plus accrued and unpaid interest, or in lieu of the premium, to convert the principal and accrued interest into Series B Convertible Preferred Shares. Notwithstanding the foregoing, the 2020 Bridge Loan Notes are not redeemable by the Company prior to maturity without explicit consent of the holder.

The Company elected to account for the notes and all their embedded features under the fair value election pursuant to ASC 815-15, *Derivatives and Hedging*. For the six months ended November 30, 2020, the Company recognized $0.5 million of change in fair value of the 2020 Bridge Loan Notes and related interest in the consolidated statements of operations and comprehensive income (loss) related to the decrease in the fair value of the 2020 Bridge Loan Notes. As of November 30, 2020 and May 31, 2020, the fair value of the 2020 Bridge Loan Notes was $1.9 million and $2.3 million, respectively.

7. Commitments and Contingencies

Series A Convertible Preferred Shares

In December 2016, the Company completed its Series A convertible preferred shares financing, converting $500,000 of the Series Seed Convertible Notes into 5,250,000 Series A convertible preferred shares (the “Series A Preferred Shares”).

Series B Convertible Preferred Shares

From December 2016 to April 2017, the Company issued 7,500,000 Series B Convertible Preferred Shares at $1.00 per share (the “Series B Convertible Preferred Shares”) for aggregate proceeds of $6.65 million, net of $99,316 of issuance costs, and the conversion of $750,000 of the Series Seed Convertible Notes (Note 6).

In December 2018, the Company issued 1,843,664 Series B Convertible Preferred Shares at $1.00 per share, providing the Company with proceeds of $1,843,664 and converted $2.1 million of the 2018 Bridge Loan Notes (Note 5) plus $56,336 accrued interest into 2,156,336 Series B Convertible Preferred Shares at $1.00 per share.

In April 2019, the Company reopened and completed an additional round of its Series B Convertible Preferred Shares financing, providing the Company with proceeds of $4,998,411, net of $1,589 of issuance costs, from the issuance of 5,000,000 Series B Convertible Preferred Shares at $1.00 per share.

Dividends

The holders of the Series A and Series B Convertible Preferred Shares are entitled to participate in a dividend in proportion to the number of shares held (pari passu with the holders of equity shares). Convertible preferred share dividends are payable when and if declared by the Company’s Board of Directors. As of November 30, 2020 and May 31, 2020, the Company’s Board of Directors has not declared any dividends on the convertible preferred stock outstanding.

Liquidation

The holders of the Series A and Series B Convertible Preferred Shares are entitled to receive liquidation preferences at the rate of $0.095 and $1.00 per share, respectively. Liquidation payments to the holders of Series A and Series B Convertible Preferred Shares shall be distributed in priority to payment to any other share class.

Conversion

Each Series A and Series B Convertible Preferred Share is convertible at any time at the option of the holder into a number of ordinary shares determined by dividing the original issue price for such series by the applicable conversion price for such series, which conversion price is subject to adjustment under certain conditions. All outstanding convertible preferred shares will be automatically converted upon the closing of firm commitment underwritten public offering.

Voting Rights

The holders of the Series A and Series B Convertible Preferred Shares are entitled to vote together with the holders of ordinary shares on all matters submitted to shareholders for a vote. Each holder of convertible preferred shares is entitled to the number of votes equal to the number of shares of ordinary shares into which such shares of convertible preferred shares could be converted at the record date for determination of the shareholders entitled to vote.

8. Shareholders’ Equity

Ordinary Shares

The Company is authorized to issue 4,513,572 and 4,526,158 shares, each having a nominal value of $0.001 as of May 31, 2020 and November 30, 2020, respectively. All of the existing issued ordinary shares are fully paid. Accordingly, no further capital may be required by the Company from the holders of such shares. The rights and restrictions to which the ordinary shares will be subject are prescribed in the Articles of Association. The Articles of Association permit the board of directors, with shareholder approval, to determine the terms of any preferred shares that may be issued. The board of directors is authorized, having obtained the consent of the shareholders, to provide from time to time the issuance of other classes or series of shares and to establish the characteristics of each class or series, including the number of shares, designations, relative voting rights,

dividend rights, liquidation and other rights, redemption, repurchase or exchange rights and any other preferences and relative, participating, optional or other rights and limitations not inconsistent with applicable law.

Ordinary shares reserved for future issuance consists of the following at May 31, 2020 and November 30, 2020:

	MAY 31, 2020	NOVEMBER 30, 2020
Conversion of preferred shares	21,750,000	21,750,000
Stock options issued and outstanding	872,833	956,133
Authorized for future option grants	142,467	59,167
	22,765,300	22,765,300

9. Equity Incentive Plan

In December 2016, the Company adopted its 2016 Equity Incentive Plan (the Plan). The Plan provides for the grant of incentive stock options and non-statutory stock options to employees, directors or consultants of the Company. Options granted under the Plan generally vest over a period of 3 years, as determined by the Board of Directors, and the maximum term of stock options granted under the Plan is 10 years. As of May 31, 2020 and November 30, 2020, the Company had 1,046,317 shares authorized for issuance under the Plan and 142,467 and 59,167 shares, respectively, remained available for grant.

Stock Options

The following table summarizes stock option activity during the six months ended November 30, 2020:

	NUMBER OF OPTIONS	WEIGHTED AVERAGE EXERCISE PRICE	WEIGHTED AVERAGE REMAINING CONTRACT LIFE IN YEARS	TOTAL AGGREGATE INTRINSIC VALUE (IN THOUSANDS)
Outstanding at May 31, 2020	872,833	$ 0.25	9.0	$ 32
Granted	83,300	0.28	9.8	—
Outstanding at November 30, 2020	956,133	$ 0.25	9.5	
Vested and expected to vest at November 30, 2020	506,022	$ 0.22	8.1	$ 32
Exercisable at November 30, 2020	506,022	$ 0.22	8.1	$ 32

The intrinsic value of a stock option is the difference between the market price of the ordinary shares at measurement date and the exercise price of the option. The weighted average grant date fair value of stock options granted during the six months ended November 30, 2020 and 2019 was $0.18 and $0, respectively, for employees and $0.18 and $0, respectively, for nonemployees.

As of November 30, 2020, total unrecognized stock-based compensation costs related to unvested employee stock options was $93, and is expected to be recognized over the weighted average period of approximately 2.0, on a straight-line basis. The Company recorded stock-based compensation expense of $0 and $26,741for the six months ended November 30, 2019 and 2020, respectively.

The following table shows the weighted average assumptions used to compute the fair value of the awards granted to employees and nonemployees, using the Black-Scholes option-pricing model.

	NOVEMBER 30,	
ASSUMPTION	**2019**	**2020**
Expected volatility	80.00%	80.00%
Expected term (years)	5.78	5.78
Expected dividend yield	0.00%	0.00%
Risk-free interest rate	2.16%	1.71%

The risk-free interest rate assumption was based on the United States Treasury's rates for U.S. Treasury zero-coupon bonds with maturities similar to those of the expected term of the award being valued. The assumed dividend yield was based on the Company's expectation of not paying dividends in the foreseeable future. For awards granted to nonemployees, the full remaining contractual term is used. The estimated volatility reflects an average volatility of comparable companies whose share prices are publicly available adjusted to align with the stage of development the Company is currently at.

10. Subsequent Events

The Company has evaluated subsequent events from the balance sheet date through August 20, 2021, the date at which the consolidated financial statements were available to be issued. Aside from the events disclosed below, the Company has determined that there are no other items to disclose.

Ventyx Biosciences, Inc. Accounting Acquirer

On February 26, 2021, Ventyx Biosciences, Inc. ("Ventyx"), a clinical-stage pharmaceutical company incorporated in the State of Delaware, acquired 100% of the then-outstanding ordinary and preferred shares of the Company and Zomagen Biosciences Ltd. ("Zomagen"). Pursuant to the terms of the Share Purchase Agreement (the "Agreement"), upon closing, Ventyx paid the shareholders of the Company in the form of equity consideration of 42,905,591 shares of Ventyx common stock, stock options and Series A-1 convertible preferred stock, which includes 5,143,425 shares of Ventyx's Series A-1 convertible preferred stock, issued upon the conversion of the 2020 Bridge Loan Notes.

CONSOLIDATED FINANCIAL STATEMENTS

ZOMAGEN BIOSCIENCES, LTD.

Years Ended December 31, 2019 and 2020
With Report of Independent Auditors

REPORT OF INDEPENDENT AUDITORS

To management and the Board of Directors
Zomagen Biosciences, Ltd.

We have audited the accompanying consolidated financial statements of Zomagen Biosciences, Ltd., which comprise the consolidated balance sheets as of December 31, 2019 and 2020, and the related consolidated statements of operations, changes in stockholders' deficit and cash flows for the years then ended, and the related notes to the consolidated financial statements.

Management's Responsibility for the Financial Statements

Management is responsible for the preparation and fair presentation of these financial statements in conformity with U.S. generally accepted accounting principles; this includes the design, implementation and maintenance of internal control relevant to the preparation and fair presentation of financial statements that are free of material misstatement, whether due to fraud or error.

Auditor's Responsibility

Our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the financial statements. The procedures selected depend on the auditor's judgment, including the assessment of the risks of material misstatement of the financial statements, whether due to fraud or error. In making those risk assessments, the auditor considers internal control relevant to the entity's preparation and fair presentation of the financial statements in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity's internal control. Accordingly, we express no such opinion. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of significant accounting estimates made by management, as well as evaluating the overall presentation of the financial statements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

Opinion

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Zomagen Biosciences, Ltd. at December 31, 2019 and 2020, and the consolidated results of its operations and its cash flows for the years then ended in conformity with U.S. generally accepted accounting principles.

/s/ Ernst & Young LLP

San Diego, California
August 20, 2021

ZOMAGEN BIOSCIENCES, LTD.

Consolidated Balance Sheets
(in thousands, except share and par value amounts)

	DECEMBER 31,	
	2019	2020
Assets		
Current assets:		
Cash and cash equivalents	$ 42	$ 160
Prepaid expenses and other assets	5	24
Total current assets	47	184
Property and equipment, net	—	7
Other long-term assets	—	8
Total assets	$ 47	$ 199
Liabilities and stockholders' deficit		
Current liabilities		
Accounts payable (includes related party amounts of $198 and $533, respectively)	$ 572	$ 602
Accrued liabilities (includes related party amounts of $159 and $3, respectively)	97	355
Convertible promissory notes- related party	1,451	1,537
Total current liabilities	2,120	2,494
Convertible SAFE notes at fair value - related party	—	3,642
Total liabilities	2,120	6,136
Stockholders' deficit:		
Share capital of $0.001 nominal value; 200 and 941,333 ordinary shares authorized and issued at December 31, 2019 and 2020, respectively; 200 and 639,261 ordinary shares outstanding at December 31, 2019 and 2020, respectively.	—	1
Additional paid-in capital	—	96
Accumulated other comprehensive income	—	1
Accumulated deficit	(2,073)	(6,035)
Total stockholders' deficit	(2,073)	(5,937)
Total liabilities and stockholders' deficit	$ 47	$ 199

See accompanying notes

ZOMAGEN BIOSCIENCES, LTD.

Consolidated Statements of Operations and Comprehensive Loss
(in thousands)

	YEARS ENDED DECEMBERE 31,	
	2019	**2020**
Operating expenses:		
Research and development (includes related party amounts of $545 and $1,059, respectively)	$ 1,650	$ 2,800
General and administrative (includes related party amounts of $305 and $436, respectively)	352	627
Total operating expenses	2,002	3,427
Loss from operations	(2,002)	(3,427)
Other income:		
Other expense	—	7
Interest expense - related party	47	86
Change in fair value of convertible SAFE notes - related party	—	442
Net loss	(2,049)	(3,962)
Other comprehensive income (loss)		
Foreign currency translation	—	1
Comprehensive loss	$ (2,049)	$ (3,961)

See accompanying notes

ZOMAGEN BIOSCIENCES, LTD.

Consolidated Statements of Stockholders' Deficit
(in thousands, except share amounts)

	ORDINARY SHARES		ADDITIONAL PAID-IN CAPITAL	ACCUMULATED OTHER COMPREHENSIVE INCOME	ACCUMULATED DEFICIT	TOTAL STOCKHOLDERS' DEFICIT
	SHARES	AMOUNT				
Balance at December 31, 2018	200	$ —	$ —	$ —	$ (24)	$ (24)
Net loss	—	—	—	—	(2,049)	(2,049)
Balance at December 31, 2019	200	$ —	$ —	$ —	$ (2,073)	$ (2,073)
Vesting of restricted ordinary shares	639,061	1	—	—	—	1
Stock-based compensation	—	—	96	—	—	96
Foreign currency translation	—	—	—	1	—	1
Net loss	—	—	—	—	(3,962)	(3,962)
Balance at December 31, 2020	639,261	$ 1	$ 96	$ 1	$ (6,035)	$ (5,937)

See accompanying notes

ZOMAGEN BIOSCIENCES, LTD.

Consolidated Statements of Cash Flows
(in thousands)

	YEARS ENDED DECEMBER 31,	
	2019	**2020**
Operating activities		
Net loss	$ (2,049)	$ (3,962)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	—	2
Stock-based compensation	—	96
Foreign exchange losses on operating cash flows	—	1
Interest expense - related party	47	86
Change in fair value of convertible SAFE notes - related party	—	442
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(4)	(27)
Accounts payable (includes related party amounts of $347 and $185, respectively)	562	30
Accrued liabilities (includes related party amounts of $9 and ($6), respectively)	97	257
Net cash used in operating activities	(1,347)	(3,075)
Investing activities		
Purchases of property and equipment	—	(8)
Net cash used in investing activities	—	(8)
Financing activities		
Proceeds from issuance of convertible promissory notes - related party	1,000	—
Proceeds from issuance of convertible SAFE notes - related party	—	3,200
Net cash provided by financing activities	1,000	3,200
Increase (decrease) in cash and cash equivalents and restricted cash	$ (347)	$ 117
Effects of exchange rate movements on cash held	—	1
Cash and cash equivalents, beginning of year	389	42
Cash and cash equivalents, end of year	$ 42	$ 160
Supplemental disclosure for non-cash activities		
Vesting of restricted stock	$ —	$ (1)

See accompanying notes

1. Organization and Summary of Significant Accounting Policies

Organization and Business

Zomagen Biosciences, Ltd. (the “Company” or “Zomagen”) is a private company, limited by shares, incorporated in England and Wales in July 2018 and has its principal operations in the United States of America. In February 2020, the Company established Zomagen Biosciences Belgium BV, a wholly owned subsidiary. The Company owns a portfolio of pre-clinical stage programs focused on high value targets of the NLRP3 inflammasome, targeting chronic inflammatory disorders. The Company is focused on building an immunology Company by selectively modulating the key immune targets to create differentiated medicines.

Liquidity and Capital Resources

The Company has experienced net losses since inception and, as of December 31, 2019 and 2020, had an accumulated deficit of $2.1 million and $6.0 million, respectively. From inception, the Company has devoted substantially all of its resources to organizing and staffing the Company, raising capital, identifying potential product candidates, undertaking research and preclinical studies and providing general and administrative support for the operations. The Company has funded all of its operations to date with proceeds from the issuance of convertible debt. At December 31, 2020, the Company had cash and cash equivalents of $160,000. On February 28, 2021, the Company was purchased by Ventyx Biosciences, Inc.; whereby, Ventyx paid the stockholders of Zomagen in the form of equity consideration of Ventyx common stock and Series A-1 convertible preferred stock (Note 11). From the date of the acquisition, Zomagen will become a wholly owned subsidiary of Ventyx. Based on the Company’s current business plan, management believes that existing cash and cash equivalents of the newly formed consolidated entity will be sufficient to fund the Company’s obligations for twelve months from the issuance of these financial statements. The accompanying financial statements have been prepared assuming the Company will continue as a going concern, which contemplates the realization of assets and settlement of liabilities in the normal course of business. The financial statements do not include any adjustments for the recovery and classification of assets or the amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

In addition to the foregoing, the Company is closely monitoring the impact of the COVID-19 pandemic on its business and has taken steps designed to protect the health and safety of its employees while continuing its operations. Given the level of uncertainty regarding the duration and impact of the COVID-19 pandemic on capital markets and the United States economy, the Company is currently unable to assess the impact of the COVID-19 pandemic on its future access to capital. The Company is continuing to monitor the spread of COVID-19 and its potential impact on the Company's operations. The full extent to which the COVID-19 pandemic will impact the Company's business, results of operations, financial condition, clinical trials, and preclinical research will depend on future developments that are highly uncertain, including actions taken to contain or treat COVID-19 and their effectiveness, as well as the economic impact on national and international markets.

Support Services Agreement with Kalika Biosciences, Inc.

In January 2019, the Company entered into a Support Services Agreement (the Support Services Agreement) with Kalika Biosciences, Inc. (“Kalika”), pursuant to which Kalika provides general administrative services, facilities support services, in addition to providing supplies and equipment and office space. The Support Services Agreement outlines the terms of the services provided by Kalika, as well as the fees and expenses charged for such services (Note 5). In February 2021, in conjunction with the acquisition of the Company by Ventyx Biosciences, Inc (“Ventyx”) (Note 11), the Company terminated its agreement with Kalika.

Basis of Presentation

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (GAAP), and include the financial statements of Zomagen Biosciences, Ltd. and Zomagen Biosciences BV. All intercompany accounts and transactions have been eliminated.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. On an ongoing basis, the Company evaluates its estimates and judgments, which are based on historical and anticipated results and trends and on various other assumptions that management believes to be reasonable under the circumstances. The most significant estimates in the Company's financial statements relate to estimates of accruals for research and development expenses, fair value measurements, valuation of embedded derivatives and the fair value of debt. By their nature, estimates are subject to an inherent degree of uncertainty and, as such, actual results may differ from management's estimates.

Foreign Currency and Currency Translation

Transactions that are denominated in a foreign currency are remeasured into the functional currency at the current exchange rate on the date of the transaction. Any foreign currency-denominated monetary assets and liabilities are subsequently remeasured at current exchange rates, with gains or losses recognized as foreign exchange gains (losses) in the consolidated statements of operations and comprehensive loss.

Cash and Cash Equivalents

Cash and cash equivalents include cash readily available in checking, savings, money market and sweep accounts. The Company considers all highly liquid investments with an original maturity of three months or less at the date of purchase to be cash equivalents.

Prepaid Expenses and Other Assets

Prepaid expenses and other assets are primarily comprised of prepayments to vendors for preclinical development costs. These costs are amortized to expense as services are performed.

Fair Value Measurements

The Company's consolidated financial instruments primarily consist of cash and cash equivalents, prepaid expenses, accounts payable and accrued liabilities. The carrying value of these financial instruments are generally considered to be representative of their respective fair values because of the short-term nature of those instruments.

The accounting guidance defines fair value, establishes a consistent framework for measuring fair value and expands disclosure for each major asset and liability category measured at fair value on either a recurring or nonrecurring basis. Fair value is defined as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability.

As a basis for considering such assumptions, the accounting guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1: Observable inputs such as quoted prices in active markets;

Level 2: Inputs, other than the quoted prices in active markets, that are observable either directly or indirectly; and

Level 3: Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

When quoted market prices are available in active markets, the fair value of assets and liabilities is estimated within Level 1 of the valuation hierarchy. If quoted prices are not available, then fair values are estimated by using pricing models, quoted prices of assets and liabilities with similar characteristics, or discounted cash flows, within Level 2 of the valuation hierarchy. In cases where Level 1 or Level 2 inputs are not available, the fair values are estimated by using inputs within Level 3 of the hierarchy. The Company had no assets measured at fair value on a recurring basis for the year ended December 31, 2019. As of December 31, 2020,

the Company had Convertible SAFE Instruments (Level 3) measured at fair value on a recurring basis as follows (in thousands):

	DECEMBER 31, 2020			
	LEVEL 1	LEVEL 2	LEVEL 3	TOTAL
Liabilities:				
Convertible SAFE Notes - related party	—	—	3,642	3,642
	$ —	$ —	$ 3,642	$ 3,642

During 2020, the Company entered into a Simple Agreement for Future Equity ("SAFE" or “Convertible SAFE Instruments). The Convertible SAFE Instruments are accounted for as a liability in accordance with ASC 480, *Distinguishing Liabilities from Equity*, and are initially recorded at fair value and remeasured each subsequent period based on Level 3 inputs. The fair value of the Convertible SAFE Instruments are based on the expected value of shares to be issued in the future to settle the obligations. The Convertible SAFE Instruments were initially recorded at the amount of consideration received as this was considered to be representative of its fair value at the date of issuance.

The carrying value of the Company’s Convertible SAFE Instruments at December 31, 2020 approximates its fair value based on the expected value of shares to be issued in the future to settle the obligation. The Company used a combination of probability analysis, which is used to establish a distribution of time to a financing or change of control and Monte Carlo simulation methods to determine the fair value of the Convertible SAFE Notes, which utilizes inputs including the common stock price, volatility of common stock, the risk-free interest rate and the probability of conversion into common shares at the conversion rate in the event of a change in control or major transaction (e.g., liquidity) (Note 6).

The following table provides a reconciliation for all liabilities measured at fair value using significant unobservable inputs (Level 3) for year ended December 31, 2020 (in thousands):

	CONVERTIBLE SAFE INSTRUMENTS
Balance at December 31, 2019	$ —
Initial fair value of Convertible SAFE Instruments at issuance	3,200
Change in fair value of Convertible SAFE Instruments	442
Balance at December 31, 2020	$ 3,642

Concentration of Credit Risk

Financial instruments, which potentially subject the Company to a concentration of credit risk, consist primarily of cash and cash equivalents. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits. The Company has not experienced any losses in such accounts and management believes that the Company is not exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held.

Property and Equipment

Property and equipment, net, which consists primarily of computers and software are stated at cost less accumulated depreciation. Depreciation is calculated using the straight-line method over the estimated useful lives of the assets (generally three to five years). Repairs and maintenance costs are charged to expense as incurred.

Long-Lived Assets

The Company reviews long-lived assets for impairment whenever events or changes in circumstances indicate the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is

measured by a comparison of the carrying amount of an asset to the future undiscounted net cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured as the amount by which the carrying amount of the assets exceeds the fair value of the assets. Fair value would be assessed using discounted cash flows or other appropriate measures of fair value. The Company did not recognize any impairment losses for the years ended December 31, 2019 and 2020.

Research and Development Expenses

The Company's research and development costs consist of salaries, payroll taxes, employee benefits, and stock-based compensation charges for those individuals involved in ongoing research and development efforts; as well as fees paid to consultants, contract research organizations, laboratory supplies, and development compound materials. All research and development costs are charged to expense as incurred.

Patent Costs

Costs related to filing and pursuing patent applications are recorded as general and administrative expenses within the Company's consolidated statements of operations and comprehensive loss and expensed as incurred as recoverability of such expenditures is uncertain.

Stock-Based Compensation

The Company accounts for stock-based compensation expense related to employee stock options and restricted stock by estimating the fair value on the date of grant. The Company estimates the fair value of these awards to employees and non-employees using the Black-Scholes option pricing model, which requires the input of highly subjective assumptions, including (a) the risk-free interest rate, (b) the expected volatility of the Company's stock, (c) the expected term of the award, and (d) the expected dividend yield. Due to the lack of an adequate history of a public market for the trading of the Company's common, the Company has based its estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded. For these analyses, the Company has selected companies with comparable characteristics, including enterprise value, risk profiles, and position within the industry, and with historical share price information sufficient to meet the expected life of the stock-based awards.

The Company has estimated the expected life of its employee stock options using the "simplified" method, whereby the expected life equals the average of the vesting term and the original contractual term of the option. The risk-free interest rates for periods within the expected life of the option are based on the yields of zero-coupon U.S. treasury securities. Under the fair value recognition provisions of the authoritative guidance for stock-based compensation awards, the Company measures the fair value of restricted stock and stock options at the grant date, and the fair value is recognized as expense on a straight-line basis over the requisite service period or contractual term. Forfeitures are recognized as incurred.

Income Taxes

The Company accounts for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements. Under this method, deferred tax assets and liabilities are determined on the basis of the differences between the financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized as income or expense in the period that includes the enactment date.

The Company recognizes net deferred tax assets to the extent that the Company believes these assets are more likely than not to be realized. In making such a determination, management considers all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax-planning strategies and results of recent operations. If management determines that the Company would be able to realize its deferred tax assets in the future in excess of their net recorded amount, management would make an adjustment to the deferred tax asset valuation allowance, which would reduce the provision for income taxes.

The Company records uncertain tax positions on the basis of a two-step process whereby (1) management determines whether it is more likely than not that the tax positions will be sustained on the basis of the technical merits of the position and (2) for those tax positions that meet the more-likely-than-not recognition threshold, management recognizes the largest amount of tax benefit that is more than 50% likely to be realized upon

ultimate settlement with the related tax authority. The Company recognizes interest and penalties related to unrecognized tax benefits within income tax expense. Any accrued interest and penalties are included within the related tax liability.

Comprehensive Income (Loss)

Comprehensive income (loss) is defined as a change in equity during a period from transactions and other events and circumstances from non-owner sources. The only component of other comprehensive income is foreign currency translation. Comprehensive gains and losses have been reflected in the consolidated statements of operations and comprehensive loss and as a separate component in the consolidated statements of stockholders' deficit.

Recently Adopted Accounting Pronouncements

During 2016, the FASB issued ASU No. 2016-01, *Recognition and Measurement of Financial Assets and Financial Liabilities* ("ASU No. 2016-01") which eliminates the requirement for companies to disclose the fair value of financial instruments measured at amortized cost on the balance sheet. Furthermore, the standard requires presentation of assets and liabilities separately, by measurement category and form of financial asset on the balance sheet or accompanying notes to the financial statements. The updated guidance is effective for annual periods beginning after December 15, 2018, and early adoption is permitted. The Company adopted this standard on January 1, 2019, which did not have a material impact on its consolidated financial statements and accompanying notes.

In August 2016, the FASB issued ASU No. 2016-15, *Statement of Cash Flows: Classification of Certain Cash Receipts and Cash Payments* ("ASU 2016-15") which includes amendments that clarify how certain cash receipts and cash payments are presented in the statement of cash flows. The new guidance also clarifies when an entity should separate cash receipts and cash payments and classify them into more than one class of cash flows. ASU 2016-15 is effective for nonpublic entities for annual periods beginning after December 15, 2018. Early adoption is permitted provided that all amendments are adopted in the same period. The Company adopted this standard on January 1, 2019, which did not have a material impact on its consolidated financial statements and accompanying notes.

In November 2017, the FASB issued ASU No. 2016-18, *Statement of Cash Flows (Topic 230) Restricted Cash* ("ASU 2016-18"). The new standard requires that the statement of cash flows explain the change during the period in the total of cash, cash equivalents and amounts described as restricted cash or restricted cash and equivalents. ASU 2016-18 is effective for fiscal years beginning after December 31, 2018, with early adoption permitted. The Company adopted this standard on January 1, 2019, which did not have a material impact on its consolidated financial statements and accompanying notes.

In August 2018, the FASB issued ASU No. 2018-13, *Changes to the Disclosure Requirements for Fair Value Measurement* ("ASU 2018-13"), which modifies certain disclosure requirements on fair value measurements. ASU 2018-13 is effective for interim and annual periods beginning after December 15, 2019, and early adoption is permitted. The Company adopted this standard on January 1, 2019. The Company has evaluated the effect that the updated standard had on its internal processes, financial statements and related disclosures, and has determined that the adoption did not have a material impact on the Company's historical financial statements.

Recent Accounting Pronouncements – Not Yet Adopted

In February 2016, the FASB issued ASU No. 2016-02, *Leases* ("ASU 2016-02"). The new standard establishes a right-of-use model and requires a lessee to recognize on the balance sheet a right-of-use asset and corresponding lease liability for all leases with terms longer than 12 months. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. ASU 2016-02 is effective for annual periods beginning after December 15, 2021 and early adoption is permitted. The Company is currently evaluating the impact that the adoption of this guidance will have on its consolidated financial statements and accompanying notes.

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments–Credit Losses: Measurement of Credit Losses on Financial Instruments* ("ASU 2016-13") which amends the impairment model by requiring entities to use a forward-looking approach based on expected losses to estimate credit losses on certain types of financial instruments, including trade receivables and available-for-sale debt securities. ASU 2016-13 is effective for annual periods beginning after December 15, 2020, with early adoption permitted. The Company is currently

evaluating the impact the adoption of this guidance will have on its consolidated financial statements and accompanying notes.

2. Property and Equipment

Property and equipment, net, consist of the following (in thousands):

	DECEMBER 31,	
	2019	2020
Computers and software	$ —	**$ 9**
Less: Accumulated depreciation	—	**(2)**
Total property and equipment, net	$ —	**$ 7**

3. Prepaid Expenses and Other Assets

Prepaid expenses and other assets consist of the following (in thousands):

	DECEMBER 31,	
	2019	2020
VAT receivable	$ 5	**$ —**
Prepaid research and development	—	**24**
Total prepaid expenses and other assets	$ 5	**$ 24**

4. Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	DECEMBER 31,	
	2019	2020
Accrued compensation	$ —	**$ 61**
Accrued research and development	88	**262**
Accrued liabilities - other	9	**32**
Total accrued liabilities	$ 97	**$ 355**

5. Other Related Party Transactions

In January 2019, the Company entered into a Support Services Agreement with Kalika Biosciences, Inc. (“Kalika”) that outlines the terms of services provided by Kalika to the Company, as well as the fees charged for such services. Kalika is a shared service company that provides administrative and research and development support services, including facilities support to the portfolio companies of New Sciences Ventures, LLC. Kalika is owned by Raju Mohan, PhD., the Chief Executive Officer of the Company, and New Science Ventures, LCC, a shareholder of the Company. The Company pays Kalika monthly for costs incurred under the agreement. Either party may terminate the support services agreement by giving 30 days’ prior notice. The support services agreement automatically renews in January of each year unless terminated by either party by giving 30 days’ prior notice.

In January 2020, the Company entered into a Research and Development Support Services Agreement with Bayside Pharma, LLC (“Bayside”) that outlines the terms of services provided by Bayside to the Company, as well as the fees charged for such services. Bayside is a research and development services company that provides certain research and development support services and facilities. Bayside is owned by an employee

of the Company. The Company pays Bayside monthly for costs incurred under the agreement. Either party may terminate the support services agreement by giving 30 days' prior notice.

Related party expense recognized by the Company under the Kalika and Bayside Support Services Agreements was as follows (in thousands):

	DECEMBER 31,	
	2019	2020
Research and development	$ 545	$ 1,059
General and administrative	305	436
Total	$ 850	$ 1,495

At December 31, 2019 and 2020, the Company had accounts payable and accrued expenses due to related parties of $356,346 and $536,168, respectively.

6. Debt – Related Parties

2018 Convertible Promissory Notes – Related Party

Between October 2018 and December 2018, the Company issued $400,000 of convertible promissory notes (the "2018 Convertible Promissory Notes") to investors, with a maturity date of April 1, 2020. The 2018 Convertible Promissory Notes accrue interest at 6% per annum, due and payable at maturity unless otherwise converted prior to maturity. The 2018 Convertible Promissory Notes are the Company's senior, unsecured obligations and are (i) equal in right of payment with the Company's future senior, unsecured indebtedness; (ii) senior in right of payment for the Company's future indebtedness; (iii) effectively subordinated to the Company's future secured indebtedness, to the extent of the value of the collateral securing that indebtedness; and (iv) structurally subordinated to all existing and future indebtedness and other liabilities, including trade payables.

The terms of the 2018 Convertible Promissory Notes provide for the principal and accrued interest to automatically convert into Series A Convertible Preferred Stock upon a qualified financing of at least $2.5 million, at a per share conversion price equal to the price per share of Series A Convertible Preferred Stock. Upon the occurrence of a sale of the Company, each holder may elect to redeem the 2018 Convertible Promissory Notes at a price equal to 2.0 multiplied by the outstanding principal plus unpaid accrued interest. Upon the occurrence of an Event of Default (as specifically defined in the agreements), at the option and upon the declaration of the holder, the outstanding principal amount and unpaid accrued interest shall become due and payable. Notwithstanding the foregoing, the 2018 Convertible Promissory Notes are not redeemable by the Company prior to maturity without the explicit consent of the holder. At December 31, 2020, the 2018 Convertible Promissory Notes were determined to be demand notes, and classified as current liabilities, as the maturity date had been exceeded.

2019 Convertible Promissory Notes – Related Party

Between April 2019 and December 2019, the Company issued $1,000,000 of convertible promissory notes (the "2019 Convertible Promissory Notes") to investors, with a maturity date of October 17, 2020. The 2019 Convertible Promissory Notes accrued interest at 6% per annum, due and payable at maturity unless otherwise converted prior to maturity. The 2019 Convertible Promissory Notes are the Company's senior, unsecured obligations and are (i) equal in right of payment with the Company's future senior, unsecured indebtedness; (ii) senior in right of payment for the Company's future indebtedness; (iii) effectively subordinated to the Company's future secured indebtedness, to the extent of the value of the collateral securing that indebtedness; and (iv) structurally subordinated to all existing and future indebtedness and other liabilities, including trade payables.

The terms of the 2019 Convertible Promissory Notes provide for the principal and accrued interest to automatically convert into the type of stock issued in a qualified financing of at least $2,500,000, at a per share conversion price based on a pre-money valuation of the Company as mutually agreed upon by the Company and holders at the time of the financing or at the holder's election, a per share conversion price equal the price

paid by investors in the financing. Upon the occurrence of a sale of the Company, each holder may elect to redeem the 2019 Convertible Promissory Notes at a price equal to 2.0 multiplied by the outstanding principal plus unpaid accrued interest. Upon the occurrence of an Event of Default (as specifically defined in the agreements), at the option and upon the declaration of the holder, the outstanding principal amount and unpaid accrued interest shall become due and payable. Notwithstanding the foregoing, the 2019 Convertible Promissory Notes are not redeemable by the Company prior to maturity without the explicit consent of the holder. At December 31, 2020, the 2019 Convertible Promissory Notes were determined to be demand notes, and classified as current liabilities, as the maturity date had been exceeded.

7. Convertible SAFE Notes – Related Party

In January 2020, the Company entered into Convertible SAFE Notes with investors that allowed for a series of advances and raised $3.2 million between January 2020 and December 2020. The Convertible Safe Notes have no maturity date and bear no interest. The holders of the Convertible Safe Notes have the right to convert the purchase amount automatically into the type of stock issued in a qualified financing of at least $2.5 million, at a per share conversion price based on a pre-money valuation of the Company as mutually agreed upon by the Company and holders at the time of the financing or at the holder's election, a per share conversion price equal the lowest price paid by investors in the financing.

Upon the occurrence of a sale of the Company or an Initial Public Offering, each holder may have elected to (i) redeem the Convertible Safe Notes at a price equal to the purchase amount together with a premium equal to the purchase amount or (i) to receive a portion of proceeds in the liquidity event or a number of shares of the Company that will be exchanged for proceeds in such events, in either case, on terms that will be negotiated in good faith by the holder and the Company. Upon an event of dissolution, the holders of the Convertible Safe Notes would receive cash payment equal to the purchase amount.

The Company determined that the Convertible Safe Notes were not legal form debt (i.e., no creditors' rights) but allowed for redemption based upon certain events that are outside of the control of the Company. The Convertible Safe Notes were classified as a marked-to-market liability pursuant to ASC 480, *Distinguishing Liabilities from Equity*. The Convertible Safe Notes were measured at fair value at issuance and each reporting period, with changes in fair value recorded within the statements of operations and comprehensive loss. For the year ended December 31, 2020, the Company recognized $0.4 million of change in fair value of the Convertible SAFE Notes in the consolidated statements of operations and comprehensive loss related to the increase in fair value of the Convertible SAFE Notes. As of December 31, 2020, the fair value of the Convertible SAFE Notes was $3.6 million.

8. Stockholders' Equity

Ordinary Shares

The Company has 941,333 issued share capital (Note 9), each having a nominal value of $0.001 at December 31, 2020 and 2019. The Articles of Association permit the board of directors, with shareholder approval, to determine the terms of any preferred shares that may be issued. The board of directors is authorized, having obtained the consent of the shareholders, to provide from time to time the issuance of other classes or series of shares and to establish the characteristics of each class or series, including the number of shares, designations, relative voting rights, dividend rights, liquidation and other rights, redemption, repurchase or exchange rights and any other preferences and relative, participating, optional or other rights and limitations not inconsistent with applicable law.

Ordinary shares reserved for future issuance is as follows at December 31, 2020:

Stock options issued and outstanding	61,333
Authorized for future option grants	330,667
	392,000

9. Equity Incentive Plan

In April 2020, the Company adopted its 2020 Equity Incentive Plan (the Plan). The Plan provides for the grant of incentive stock options, non-statutory stock options, and restricted stock awards to employees, directors or consultants of the Company. The Plan provides that the maximum aggregate number of ordinary shares reserved and available for issuance under the Plan is 392,000. Options granted under the Plan generally vest over a period of 3 years, as determined by the Board of Directors, and the maximum term of stock options granted under the Plan is 10 years. During the year ending December 31, 2020, the Company issued 61,333 stock options to employees. As of December 31, 2020, 330,667 shares remained available for grant.

Stock Options

The following table summarizes stock option activity during the year ended December 31, 2020:

	NUMBER OF OPTIONS	WEIGHTED AVERAGE EXERCISE PRICE	WEIGHTED AVERAGE REMAINING CONTRACT LIFE IN YEARS	TOTAL AGGREGATE INTRINSIC VALUE (IN THOUSANDS)
Outstanding at December 31, 2019	—	$ —	—	$ —
Granted	61,333	0.10		
Outstanding at December 31, 2020	61,333	$ 0	10.0	$ 9
Vested and expected to vest at December 31 2020	15,333	$ 0	10.0	$ 2
Exercisable at December 31, 2020	15,333	$ 0	10.0	$ 2

The intrinsic value of a stock option is the difference between the market price of the common stock at measurement date and the exercise price of the option. The weighted average grant date fair value of stock options granted during the years ended December 31, 2019 and 2020 was $0.00 and $0.25, respectively, per share. There were no stock options exercised during the years ended December 31, 2019 and 2020. At December 31, 2020 and 2019, there were no stock options granted to nonemployees.

As of December 31, 2019 and 2020, total unrecognized stock-based compensation costs related to unvested employee stock options was $0 and $10,172, respectively, and is expected to be recognized over the weighted average period of approximately 0 and 2.2 years, respectively, on a straight-line basis. The Company will record stock-based compensation expense commencing in January 2021, in accordance with the normal vesting schedule.

The following table shows the weighted average assumptions used to compute the fair value of the awards granted to employees and nonemployees, using the Black-Scholes option-pricing model:

ASSUMPTION	DECEMBER 31, 2020
Expected volatility	80.00%
Expected term (years)	5.3 - 6.1
Expected dividend yield	0.00%
Risk-free interest rate	0.55%

The risk-free interest rate assumption was based on the United States Treasury's rates for U.S. Treasury zero-coupon bonds with maturities similar to those of the expected term of the award being valued. The assumed dividend yield was based on the Company's expectation of not paying dividends in the foreseeable future. For awards granted to nonemployees, the full remaining contractual term is used. The estimated volatility reflects

an average volatility of comparable companies whose share prices are publicly available adjusted to align with the Company's stage of development.

Restricted Ordinary Shares

In July 2018, the Company Issued 200 Ordinary shares to the founders of the Company. In April 2020, the Company issued 941,133 ordinary shares as restricted share awards with a weighted average grant date fair value of $0.15 to various employees, advisors and directors of the Company, which vest over a period of zero to three years. The Company recorded stock-based compensation expense of $0 and $96,585 for the years ended December 31, 2019 and 2020, respectively, which has been reported in the Company's statements of operations and comprehensive loss.

As of December 31, 2019 and 2020, 200 and 639,261, respectively, of those restricted share awards were vested. Upon the termination of service of a restricted stockholder, any unvested shares are automatically converted into deferred shares. During the years ended December 31, 2019 and 2020, 0 and 20,000 shares, respectively, were converted into deferred shares.

The Company has recorded an immaterial amount of liability for the years ended December 31, 2019 and 2020 related to the unvested restricted share awards subject to repurchase. The Company reduces the liability as the underlying shares vest. At December 31, 2019 and 2020, 0 and 282,072 shares, respectively, subject to repurchase remained unvested.

The following table summarizes restricted share activity for the year ended December 31, 2020:

	RESTRICTED ORDINARY SHARES		WEIGHTED AVERAGE GRANT DATE FAIR VALUE
Balance at December 31, 2019	200	$	0.001
Granted	941,133		0.15
Vested	(639,261)		(0.15)
Cancelled / Forfeited	(20,000)		(0.15)
Balance at December 31, 2020	**282,072**	$	0.15

10. Income Taxes

A reconciliation of income tax provision to amounts computed by applying the United Kingdom ("U.K."), statutory income tax rate to loss from continuing operations before income taxes is shown as follows:

	DECEMBER 31,	
	2019	2020
Statutory federal income tax rate	19.0%	18.8%
Valuation allowance	(18.5)%	(16.0)%
Other	(0.5)%	(2.8)%
Effective income tax rate	0.0%	0.0%

The Company's deferred tax assets as of December 31, 2020 and 2019 are summarized below (in thousands):

	DECEMBER 31,	
	2019	2020
Pre-trading expenditures	$ 378	$ 918
Other	10	$ 27
Valuation allowance	(388)	$ (945)
Total deferred tax balances	$ —	$ —

For the year ended December 31, 2019 and 2020, the Company had U.K. pre-trading expenditures of approximately $2.0 million and $4.8 million, respectively. All expenditures were incurred after July 2018. Tax relief for pre-trading expenditures is generally limited to the expenditures incurred in the seven years prior to trade commencing.

Due to the Company's history of losses and uncertainty regarding future earnings, a valuation allowance has been recorded against the Company's deferred tax assets, as it is not more likely than not that such assets will be realized.

The Company recognizes a tax benefit from an uncertain tax position when it is more likely than not that the position will be sustained. The Company had no accrual for uncertain tax positions or interest and penalties on uncertain tax positions for the years ended December 31, 2019 and 2020. The Company records interest and penalties as a component of income tax expense, if applicable.

U.K. tax authorities may raise an inquiry into a submitted return within two years from the end of the tax year. The Company has not been, nor is it currently, under examination by any income tax authority. The inquiry window for the company's 2019 and 2020 U.K. tax returns closes on December 31, 2021 and 2022, respectively.

11. Subsequent Events

The Company has evaluated subsequent events from the balance sheet date through August 20, 2021, the date at which the consolidated financial statements were available to be issued. Aside from the events disclosed below, the Company has determined that there are no other items to disclose.

Ventyx Biosciences, Inc. Accounting Acquirer

On February 26, 2021, Ventyx Biosciences, Inc., a clinical-stage pharmaceutical company incorporated in the State of Delaware, acquired 100% of the then-outstanding ordinary shares of the Company. Pursuant to the terms of the Share Purchase Agreement upon closing, Ventyx paid the shareholders of the Company in the form of equity consideration a total of 23,836,443 shares of Ventyx common stock, stock options and Series A-1 convertible preferred stock, which includes 5,209,858 and 13,954,978 shares for the conversion of the Company's then-outstanding Convertible Promissory Notes and Convertible SAFE Notes, respectively.

UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL INFORMATION

On February 26, 2021, concurrent with the closing of the Company's Series A financing for gross proceeds of $57.3 million, the Company acquired 100% of the issued and outstanding shares of two affiliated companies, Zomagen and Oppilan, or the Acquisitions. The following unaudited pro forma condensed combined financial statements are based on the audited historical consolidated financial statements of Zomagen and Oppilan, which are included in this prospectus, after giving effect to the Acquisitions, and prepared based upon the acquisition method of accounting in accordance with GAAP. Ventyx was determined to be the acquirer of Zomagen and Oppilan for accounting purposes. See "*Note 2 – Basis of presentation*" below. To determine the accounting for this transaction under GAAP, the Company assessed whether the integrated sets of assets and activities should be accounted for as an acquisition of a business or an asset acquisition. The guidance requires an initial screen test to determine if substantially all of the fair value of the gross assets acquired is concentrated in a single asset or group of similar assets. If that screen is met, the set is not a business. In connection with the Acquisitions, Zomagen and Oppilan do not have an organized workforce that significantly contributes to their ability to create output, and substantially all of the fair value is concentrated in cash and IPR&D. As such, the Acquisitions have been accounted for as asset acquisitions.

The unaudited pro forma condensed combined statement of operations and comprehensive loss is based on the Company's audited historical consolidated financial statements and the audited historical consolidated financial statements of Zomagen and Oppilan, which are included in this prospectus. The unaudited pro forma condensed combined statement of operations and comprehensive loss gives effect to the Acquisitions as if such acquisitions had occurred on January 1, 2020 and combines the historical audited consolidated statement of operations of Ventyx and Zomagen for the fiscal year ended December 31, 2020 with the adjusted historical consolidated statement of operations of Oppilan for the trailing twelve months ended November 30, 2020. Oppilan's financial statements for the trailing twelve months ended November 30, 2020 was derived by taking Oppilan's historical results of operations for the fiscal year ended May 31, 2020, deducting Oppilan's historical results of operations for the six months ended November 30, 2019 and adding Oppilan's historical results of operations for the six months ended November 30, 2020.

The unaudited pro forma condensed statement of operations for the six months ended June 30, 2021 combines the historical unaudited condensed consolidated operations of Ventyx for the six months ended June 30, 2021, with the historical consolidated statement of operations of Zomagen and Oppilan for the period from January 1, 2021 to February 25, 2021. Zomagen's and Oppilan's results for the period from February 26, 2021 to June 30, 2021 are included within the Ventyx's consolidated statement of operations for the six months ended June 30, 2021.

An unaudited pro forma condensed combined balance sheet has not been presented as the Acquisitions were reflected in the Company's balance sheet as of June 30, 2021. The unaudited pro forma condensed combined financial statements include all material pro forma adjustments necessary for this purpose that are directly attributable to the Acquisitions and are factually supportable.

The unaudited pro forma condensed combined financial information was derived from and should be read in conjunction with the following historical financial statements and notes: (a) the audited consolidated financial statements of Ventyx for the years ended December 31, 2019 and 2020 contained elsewhere within this document; (b) the audited consolidated financial statements of Zomagen for the years ended December 31, 2019 and 2020, and Oppilan for the years ended May 31, 2019 and 2020, respectively, contained elsewhere within this document; (c) the unaudited condensed consolidated financial statements of Ventyx for the six month period ended June 30, 2020 and 2021, contained elsewhere within this document, and (d) the unaudited condensed consolidated financial statements of Oppilan for the six months ended November 30, 2019 and 2020, contained elsewhere in this document.

The pro forma financial information has been prepared by Ventyx in accordance with Article 11 of Regulation S-X (Pro Forma Financial Information). The unaudited pro forma condensed combined financial information is provided for illustrative purposes only, does not necessarily reflect what the actual consolidated results of operations would have been had the Acquisitions occurred on the dates assumed and may not be useful in predicting the future consolidated results of operations or financial position. Ventyx's results of operations and actual financial position may differ significantly from the pro forma amounts reflected herein due to a variety of factors.

UNAUDITED PRO FORMA CONDENSED COMBINED STATEMENT OF OPERATIONS
FOR THE SIX MONTHS ENDED JUNE 30, 2021
(In thousands, except per share amounts)

	VENTYX BIOSCIENCES, INC	ZOMAGEN BIOSCIENCES, LTD	OPPILAN PHARMA, LTD	TRANSACTION ACCOUNTING ADJUSTMENTS	NOTES	PRO FORMA COMBINED
Operating expenses:						
Research and development	34,112	730	(15)	(21,781)	F	13,046
General and administrative	4,071	152	353	—		4,576
Total operating expenses	38,183	882	338	(21,781)		17,622
Loss from operations	(38,183)	(882)	(338)	27,781		(17,622)
Other (income) expense:						
Other (income) expense	44	—	—	—		44
Interest expense - related party	99	287	—	—	J	386
Change in fair value of related party notes	11,051	—	—	(11,051)	G	—
Change in fair value of Series A tranche liability	3,972	—	—	(3,972)	H	—
Change in fair value of 2020 bridge loan notes	—	—	(139)	139	I	—
Total other (income) expense	15,166	287	(139)	(14,884)		430
Net loss	$ (53,349)	$ (1,169)	$ (199)	$ 36,665		$ (18,052)
Net loss per share - basic and diluted	$ (1.80)					$ (0.56)
Shares used to compute basic and diluted net loss per share	29,607,406			2,422,990	K	32,030,396

See accompanying notes to the unaudited pro forma condensed combined financial information.

UNAUDITED PRO FORMA CONDENSED COMBINED STATEMENT OF OPERATIONS
FOR THE TWELVE MONTHS ENDED DECEMBER 31, 2020
(In thousands, except per share amounts)

	VENTYX BIOSCIENCES, INC	ZOMAGEN BIOSCIENCES, LTD	OPPILAN PHARMA, LTD	TRANSACTION ACCOUNTING ADJUSTMENTS	NOTES	PRO FORMA COMBINED
Operating expenses:						
Research and development	6,366	2,800	(91)	21,781	A	30,856
General and administrative	684	627	1,399	—		2,710
Total operating expenses	7,050	3,427	1,308	21,781		33,566
Loss from operations	(7,050)	(3,427)	(1,308)	(21,781)		(33,566)
Other (income) expense:						
Other (income) expense	1	7	(5)	—		3
Interest expense - related party	358	86	—	—	E	444
Change in fair value of related party notes	20,765	442	—	(21,207)	C	—
Change in fair value of 2020 bridge loan notes	—	—	(639)	639	D	—
Total other (income) expense	21,124	535	(644)	(20,568)		447
Net loss	$ (28,174)	$ (3,962)	$ (664)	$ (1,213)		$ (34,013)
Net loss per share - basic and diluted	$ (1.48)					$ (1.27)
Shares used to compute basic and diluted net loss per share	19,022,848			7,831,449	B	26,854,297

See accompanying notes to the unaudited pro forma condensed combined financial information.

NOTES TO THE UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL INFORMATION

1. Description of the Zomagen and Oppilan acquisition

The Company is a clinical-stage biopharmaceutical company developing a pipeline of small molecule product candidates to address a range of inflammatory diseases with significant unmet medical need. The Company leverages the substantial experience of its team in immunology to identify important new targets and to develop differentiated therapeutics against these targets. The Company's clinical product candidates address therapeutic indications with established multi-billion-dollar potential and substantial commercial opportunity for novel first-in-class or best-in-class molecules

In February 2021, the Company received $57.3 million in cash in connection with a Series A preferred stock financing, and an additional $57 million in June 2021 in connection with a second closing of the same Series A preferred stock financing. Concurrent with the Series A Financing in February 2021, the Company acquired all of the issued and outstanding shares of two affiliated companies, Zomagen and Oppilan.

In connection with the closing of Ventyx's acquisition of Zomagen, on February 26, 2021, the Company issued an aggregate of (i) 19,164,836 shares of our Series A-1 preferred stock for the exchange for Zomagen's then-outstanding convertible promissory notes and convertible simple agreements for future equity ("SAFE") notes, (ii) 4,380,030 shares of our common stock, and (iii) 291,577 options to purchase shares of our common stock, in exchange for all of the outstanding shares and options of Zomagen.

In connection with the closing of Ventyx's acquisition of Oppilan, on February 26 2021, the Company issued an aggregate of (i) 38,727,626 shares of our Series A-1 preferred stock for the exchange for Oppilan's then-outstanding equity and convertible promissory notes, (ii) 3,451,419 shares of our common stock, and (iii) 726,544 options to purchase shares of our common stock, in exchange for all of the outstanding shares and options of Oppilan.

2. Basis of presentation

The accompanying unaudited pro forma condensed combined financial information gives effect to the acquisition of Zomagen and Oppilan by Ventyx. The unaudited pro forma condensed combined financial information is based on the historical consolidated financial statements Ventyx, Zomagen and Oppilan, and the assumptions and adjustments set forth in these notes. In accordance with the financial statement requirements contained in Article 11 of Regulation S-X, pro forma condensed combined financial information is presented as outlined below:

- The unaudited pro forma condensed statement of operations for the year ended December 31, 2020 is presented as if Ventyx's acquisition of Zomagen and Oppilan had occurred on January 1, 2020, and combines the historical audited consolidated statement of operations of Ventyx and Zomagen for the fiscal year ended December 31, 2020 with the adjusted historical consolidated statement of operations of Oppilan for the trailing twelve months ended November 30, 2020. Oppilan's adjusted historical consolidated statement of operations for the trailing twelve months ended November 30, 2020 was derived by taking Oppilan's historical results of operations for the fiscal year ended May 31, 2020, deducting Oppilan's historical results of operations for the six months ended November 30, 2019 and adding Oppilan's historical results of operations for the six months ended November 30, 2020.
- The unaudited pro forma condensed statement of operations for the six months ended June 30, 2021 combines the historical unaudited condensed consolidated operations of Ventyx for the six months ended June 30, 2021, with the historical consolidated statement of operations of Zomagen and Oppilan for the period from January 1, 2021 to February 25, 2021. Zomagen's and Oppilan's results for the period from February 26, 2021 to June 30, 2021 are included within the Ventyx's consolidated statement of operations for the six months year ended June 30, 2021.

The unaudited pro forma condensed combined financial information is provided for informational purposes only and is based on available information and reasonable assumptions. It does not purport to represent what the actual consolidated results of operations or the consolidated financial position of Ventyx would have been if the acquisition occurred on the dates indicated, nor is it necessarily indicative of future consolidated results of

operations or consolidated financial position. The actual financial position and results of operations will differ, perhaps significantly, from the pro forma amounts reflected herein due to a variety of factors, including access to additional information, changes in value not currently identified and changes in financial position and operating results following the date of the unaudited pro forma condensed combined financial information.

Pro forma transaction accounting adjustments are included only to the extent they are adjustments that reflect the accounting for the Transaction in accordance with GAAP.

The acquisition will be accounted for using the asset acquisition method of accounting with Ventyx as the accounting acquirer and Zomagen and Oppilan as the accounting acquirees.

The unaudited pro forma condensed combined financial information should be read in conjunction with the historical consolidated financial statements and accompanying notes of Ventyx included within this prospectus.

3. Preliminary purchase price

The fair value of the purchase price in the unaudited pro forma condensed combined financial information below is based on the Ventyx's value per share of $0.32 per share of common stock and Series A-1 share, and $0.31 per outstanding option to purchase shares of Ventyx common stock on February 26, 2021.

The following table summarizes the components of the purchase price for Zomagen and Oppilan:

	ZOMAGEN BIOSCIENCES, LTD	OPPILAN PHARMA, LTD
Ventyx common shares issued	4,380,030	3,451,419
Ventyx's share value	$ 0.32	$ 0.32
	$ 1,401,610	$ 1,104,454
Ventyx Series A-1 shares issued	19,164,836	38,727,626
Ventyx's Series A-1 share value	$ 0.32	$ 0.32
	6,132,748	12,392,840
Stock consideration	$ 7,534,357	$ 13,497,294
Outstanding options to purchase shares of Ventyx common stock	291,577	726,544
Ventyx's option value	$ 0.31	$ 0.31
	$ 90,389	$ 225,229
Transaction fees	$ 206,647	$ 370,195
Total purchase price	$ 7,831,393	$ 14,092,718

This purchase price has been used to prepare the Transaction accounting adjustments in the unaudited pro forma condensed combined financial information.

4. Transaction accounting adjustments

Adjustments included in the column under the headings "Transaction accounting adjustments" in the statement of operations for the twelve months ended December 31, 2020 and six months ended June 30, 2021 depict the accounting for the acquisition required by GAAP, assuming those adjustments were made as of January 1, 2020. Transaction accounting adjustments reflect the application of required accounting to the Transaction applying the effects of the acquisition of Zomagen and Oppilan to Ventyx's historical financial information.

The Transaction accounting adjustments included in the unaudited pro forma condensed combined financial information for the year ended December 31, 2020 are as follows:

A. To recognize an expense in relation to the intangible identifiable research and development assets with no alternative future use (i.e. an excess of the Cost of Acquisition over the acquired net assets of Zomagen and Oppilan).
B. To reflect the issuance of Ventyx Common Stock for the Stock Consideration to Zomagen and Oppilan stockholders. The issuance of 4,380,030 and 3,451,419 shares of Stock Consideration to Zomagen and Oppilan stockholders, respectively, is reflected in the shares used to calculate net loss per share.
C. To reverse the change in fair value of related party notes of $20,765 and $442 for Ventyx and Zomagen, respectively, as this fair value adjustment will not be a recurring transaction in the post-acquisition period.
D. To reverse the change in fair value of 2020 bridge loan notes of $639 for Oppilan, as this gain will not be a recurring transaction in the post-acquisition period.
E. To reverse the interest expense of $86 for Zomagen related to the fair value adjustments to the SAFE and convertible promissory Notes.

The Transaction accounting adjustments included in the unaudited pro forma condensed combined financial information for the six months ended June 30, 2021 are as follows:

F. To reverse the expense in relation to the intangible identifiable research and development assets with no alternative future use (i.e. an excess of the Cost of Acquisition over the acquired net assets of Zomagen and Oppilan) that was recognized during the six months ended June 30, 2021.
G. To reverse the change in fair value of related party notes of $11,051 for Ventyx, as this fair value adjustment will not be a recurring transaction in the post-acquisition period.
H. To reverse the change in fair value of Series A tranche liability of $3,972 for Ventyx, as this fair value adjustment will not be a recurring transaction in the post-acquisition period.
I. To reverse the change in fair value of 2020 bridge loan notes of $139 for Oppilan, as this gain will not be a recurring transaction in the post-acquisition period.
J. To reverse the interest expense of $287 for Zomagen related to the fair value adjustments to the SAFE and convertible promissory Notes.
K. To reflect the issuance of Ventyx common stock for the Stock Consideration to Zomagen and Oppilan stockholders as if the transaction occurred on January 1, 2020, the issuance of 4,380,030 and 3,451,419 shares of Stock Consideration to Zomagen and Oppilan stockholders, respectively, had previously been reflected in the shares used to calculate net loss per share as of the dates of the Acquisitions.

Shares

Ventyx Biosciences, Inc.

Common Stock

PRELIMINARY PROSPECTUS

Jefferies

Evercore ISI

Piper Sandler

LifeSci Capital

, 2021

PART II
INFORMATION NOT REQUIRED IN THE PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution

The following table sets forth the expenses to be incurred in connection with the offering described in this Registration Statement, other than underwriting discounts and commissions, all of which will be paid by us. All amounts are estimates except the Securities and Exchange Commission's registration fee, the Financial Industry Regulatory Authority, Inc.'s filing fee and the Nasdaq listing fee.

	AMOUNT TO BE PAID
SEC Registration Fee	$ *
FINRA filing fee	*
Nasdaq listing fee	*
Printing and engraving expenses	*
Legal fees and expenses	*
Accounting fees and expenses	*
Transfer agent and registrar fees	*
Miscellaneous expenses	*
Total	$ *

* To be completed by amendment.

Item 14. Indemnification of Directors and Officers

Section 145 of the Delaware General Corporation Law empowers a corporation to indemnify its directors and officers and to purchase insurance with respect to liability arising out of their capacity or status as directors and officers, provided that the person acted in good faith and in a manner the person reasonably believed to be in the Companys best interests, and, with respect to any criminal action, had no reasonable cause to believe the person's actions were unlawful. The Delaware General Corporation Law further provides that the indemnification permitted thereunder shall not be deemed exclusive of any other rights to which the directors and officers may be entitled under the corporation's bylaws, any agreement, a vote of stockholders or otherwise. The certificate of incorporation of the registrant to be in effect upon the completion of this offering provides for the indemnification of the registrant's directors and officers to the fullest extent permitted under the Delaware General Corporation Law. In addition, the bylaws of the registrant to be in effect upon the completion of this offering require the registrant to fully indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding (whether civil, criminal, administrative or investigative) by reason of the fact that such person is or was a director or officer of the registrant, or is or was a director or officer of the registrant serving at the registrant's request as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorney's fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with such action, suit or proceeding, to the fullest extent permitted by applicable law.

Section 102(b)(7) of the Delaware General Corporation Law permits a corporation to provide in its certificate of incorporation that a director of the corporation shall not be personally liable to the corporation or its stockholders for monetary damages for breach of fiduciary duty as a director, except (1) for any breach of the director's duty of loyalty to the corporation or its stockholders, (2) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (3) for payments of unlawful dividends or unlawful stock repurchases or redemptions or (4) for any transaction from which the director derived an improper personal benefit. The registrant's certificate of incorporation to be in effect upon the completion of this offering provides that the registrant's directors shall not be personally liable to it or its stockholders for monetary damages for breach of fiduciary duty as a director and that if the Delaware General Corporation Law is amended to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of the registrant's directors shall be eliminated or limited to the fullest extent permitted by the Delaware General Corporation Law, as so amended.

Section 174 of the Delaware General Corporation Law provides, among other things, that a director who willfully or negligently approves of an unlawful payment of dividends or an unlawful stock purchase or redemption may be held liable for such actions. A director who was either absent when the unlawful actions were approved, or dissented at the time, may avoid liability by causing his or her dissent to such actions to be entered in the books containing minutes of the meetings of the board of directors at the time such action occurred or immediately after such absent director receives notice of the unlawful acts.

As permitted by the Delaware General Corporation Law, the registrant intends to enter into separate indemnification agreements with each of the registrant's directors and certain of the registrant's officers which would require the registrant, among other things, to indemnify them against certain liabilities which may arise by reason of their status as directors, officers or certain other employees.

The registrant expects to obtain and maintain insurance policies under which its directors and officers are insured, within the limits and subject to the limitations of those policies, against certain expenses in connection with the defense of, and certain liabilities which might be imposed as a result of, actions, suits or proceedings to which they are parties by reason of being or having been directors or officers. The coverage provided by these policies may apply whether or not the registrant would have the power to indemnify such person against such liability under the provisions of the Delaware General Corporation Law.

These indemnification provisions and the indemnification agreements intended to be entered into between the registrant and the registrant's officers and directors may be sufficiently broad to permit indemnification of the registrant's officers and directors for liabilities (including reimbursement of expenses incurred) arising under the Securities Act of 1933, as amended.

The underwriting agreement between the registrant and the underwriters to be filed as Exhibit 1.1 to this registration statement provides for the indemnification by the underwriters of the registrant's directors and officers and certain controlling persons against specified liabilities, including liabilities under the Securities Act with respect to information provided by the underwriters specifically for inclusion in the registration statement.

Item 15. Recent Sales of Unregistered Securities

The following list sets forth information regarding all unregistered securities sold by us since January 1, 2018. No underwriters were involved in the sales and the certificates representing the securities sold and issued contain legends restricting transfer of the securities without registration under the Securities Act or an applicable exemption from registration.

(1) In June 2021, the Company issued and sold an aggregate of 59,782,399 shares of its Series A preferred stock at a purchase price of $0.9534578 per share for aggregate proceeds of approximately $57.0 million to a total of thirteen (13) accredited investors.

(2) In February 2021, the Company issued and sold an aggregate of 60,097,042 shares of its Series A preferred stock at a purchase price of $0.9534578 per share for aggregate proceeds of approximately $57.3 million to a total of fourteen (14) accredited investors.

(3) In February 2021, the Company issued 9,700,856 shares of its restricted common stock in exchange for a portion of the purchase paid by an investor in connection with the purchase of its Series A preferred stock.

(4) connection with the closing of Ventyx's acquisition of Oppilan, on February 26 2021, the Company issued an aggregate of (i) 38,727,626 shares of our Series A-1 preferred stock for the exchange for Oppilan's then-outstanding equity and convertible promissory notes, (ii) 3,451,419 shares of our common stock, and (iii) 726,544 options to purchase shares of our common stock, in exchange for all of the outstanding shares and options of Oppilan.

(5) In connection with the closing of Ventyx's acquisition of Zomagen, on February 26, 2021, the Company issued an aggregate of (i) 19,164,836 shares of our Series A-1 preferred stock for the exchange for Zomagen's then-outstanding convertible promissory notes and convertible simple agreements for future equity ("SAFE") notes, (ii) 4,380,030 shares of our common stock, and (iii) 291,577 options to purchase shares of our common stock, in exchange for all of the outstanding shares and options of Zomagen.

(6) In February 2021, the Company issued an aggregate of 121,597,908 shares of its Series A-1 preferred stock in connection with the conversion of its outstanding convertible promissory notes and simple agreements for future equity.

(7) In February 2019, the Company issued an aggregate of 2,665,633 shares of its common stock at a purchase price of $0.0001 per share, for aggregate consideration of $267.00.

(8) In November 2018, the Company issued an aggregate of 200 shares of its common stock at a purchase price of $0.01, for aggregate consideration of $2.00.

(9) From March 2019 through the date of this prospectus, the Company granted stock options to purchase an aggregate of shares of its common stock at a weighted-average exercise price of $ per share, to certain of its employees and consultants in connection with services provided to us by such persons. of these options have been canceled and have been exercised through the date of this prospectus.

The offers, sales and issuances of the securities described in Items 15(1), 15(2), 15(3), 15(4)(i), 15(4)(ii), 15(5)(i), 15(5)(ii), 15(6), 15(7) and 15(8) were exempt from registration under the Securities Act under Section 4(a)(2) of the Securities Act or Regulation D promulgated thereunder as transactions by an issuer not involving a public offering. The recipients of securities in each of these transactions acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities issued in these transactions. Each of the recipients of securities in these transactions was an accredited person and had adequate access, through employment, business or other relationships, to information about the registrant.

The offers, sales and issuances of the securities described in Item 15(4)(iii), 15(5)(iii) and 15(9) were exempt from registration under the Securities Act under either (1) Rule 701 in that the transactions were under compensatory benefit plans and contracts relating to compensation as provided under Rule 701 or (2) Section 4(a)(2) of the Securities Act as transactions by an issuer not involving any public offering. The recipients of such securities were the registrant's employees, consultants or directors and received the securities under the Company's 2019 Plan. The recipients of securities in each of these transactions represented their intention to acquire the securities for investment only and not with view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities issued in these transactions.

Item 16. Exhibit and Financial Statement Schedules

(a) Exhibits.

See the Exhibit Index immediately preceding the signature page hereto for a list of exhibits filed as part of this registration statement on Form S-1, which Exhibit Index is incorporated herein by reference.

(b) Financial Statement Schedules

Schedules have been omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or notes thereto.

Item 17. Undertakings

The undersigned registrant hereby undertakes to provide to the underwriters at the closing specified in the underwriting agreements, certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is

against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

The undersigned hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act of 1933 shall be deemed to be part of this registration statement as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

EXHIBIT INDEX

Exhibit Number	Description
1.1*	Form of Underwriting Agreement, including form of Lock-up Agreement.
3.1*	Amended and Restated Certificate of Incorporation of the Registrant, as currently in effect.
3.2*	Form of Amended and Restated Certificate of Incorporation of the Registrant, to be in effect upon the completion of this offering.
3.3*	Amended and Restated Bylaws of the Registrant, as currently in effect.
3.4*	Form of Amended and Restated Bylaws of the Registrant, to be in effect upon the completion of this offering.
4.1*	Investors' Rights Agreement, dated as of February 26, 2021, by and among the Registrant and certain of its Stockholders.
4.2*	Specimen common stock certificate of the Registrant.
5.1*	Opinion of Wilson Sonsini Goodrich & Rosati, Professional Corporation.
10.1*	Form of Indemnification Agreement
10.2+*	2019 Equity Incentive Plan, as amended, and forms of agreement thereunder.
10.3+*	2021 Equity Incentive Plan and forms of agreements thereunder, to be in effect upon the completion of this offering.
10.3+*	2021 Employee Stock Purchase Plan, to be in effect upon the completion of this offering.
10.4+*	Executive Employment Agreement, dated as of May 11, 2021, by and between Raju Mohan, Ph.D. and the Registrant.
10.5+*	Offer Letter, dated as of March 1, 2021, by and between Christopher Krueger, J.D., M.B.A. and the Registrant.
10.6+*	Offer Letter, dated as of March 1, 2021, by and between John Nuss, Ph.D. and the Registrant.
10.7+*	Offer Letter, dated as of April 21, 2021, by and between Martin Auster, M.D. and the Registrant.
10.8+*	Executive Chairperson Services Agreement, dated as of May 14, 2021, by and between Sheila Gujrathi, M.D. and the Registrant.
10.9+*	Offer Letter, dated as of May 21, 2021, by and between William R. White, J.D., M.P.P. and the Registrant.
10.10*	Lease, dated as of June 14, 2021, by and between Charlotte Partners, Inc. and the Registrant.
10.11*	Asset Purchase Agreement, dated as of February 7, 2019, by and between Vimalan Biosciences, Inc. and the Registrant.
21.1*	Subsidiaries of the Registrant.
23.1*	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm.
23.2*	Consent of Wilson Sonsini Goodrich & Rosati, Professional Incorporation (included in Exhibit 5.1).
24.1*	Powers of Attorney (included in page II-7 to this registration statement).

* To be filed by amendment.
\+ Indicated management contract or compensatory plan.
\# Portions of the exhibit have been omitted as the Registrant has determined that: (i) the omitted information is not material; and (ii) the omitted information would likely cause competitive harm to the Registrant if publicly disclosed.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in Encinitas, California on , 2021.

VENTYX BIOSCIENCES, INC.

By: _____
Name: Raju Mohan, Ph.D.
Title: Chief Executive Officer

KNOW ALL MEN BY THESE PRESENTS that each person whose signature appears below hereby constitutes and appoints Raju Mohan, Ph.D. and Martin Auster, M.D. as his or her true and lawful attorneys-in-fact and agents, with full power to act separately and full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this registration statement and all additional registration statements pursuant to Rule 462(b) under the Securities Act of 1933, as amended, and to file the same, with all exhibits thereto, and all other documents in connection therewith, with the Securities and Exchange Commission, granting unto each said attorney-in-fact and agent full power and authority to do and perform each and every act in person, hereby ratifying and confirming all that said attorneys-in-fact and agents or either of them or his or her or their substitute or substitutes may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed by the following persons in the capacities and on the dates indicated:

Signature	Title of Capacities	Date
Raju Mohan, Ph.D.	Chief Executive Officer and Director *(Principal Executive Officer)*	, 2021
Martin Auster, M.D.	Chief Financial Officer *(Principal Financial Accounting Officer)*	, 2021
Sheila Gujrathi, M.D.	Chair of the Board	, 2021
Jigar Choksey, M.B.A.	Director	, 2021
Richard Gaster, M.D., Ph.D.	Director	, 2021
Aaron Royston, M.D., M.B.A.	Director	, 2021
Somasundaram Subramaniam, M.B.A.	Director	, 2021
William White J.D., M.P.P.	Director	, 2021