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As confidentially submitted to the Securities and Exchange Commission on February 10, 2023.

This draft registration statement has not been publicly filed with the
Securities and Exchange Commission and all information herein remains strictly confidential.

Registration No. 333-

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

ACELYRIN, INC.
(Exact name of registrant as specified in its charter)

Delaware	2834	85-2406735
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

ACELYRIN, INC.
4149 Liberty Canyon Road
Agoura Hills, California 91301
(805) 730-0360
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Shao-Lee Lin, M.D., Ph.D.
Chief Executive Officer
4149 Liberty Canyon Road
Agoura Hills, California 91301
(805) 730-0360
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Chadwick Mills **Charles S. Kim** **Anitha Anne** **Cooley LLP** **3 Embarcadero Center, 20th Floor** **San Francisco, California 94111** **(415) 693-2000**	**Mardi C. Dier** **Chief Financial Officer and Chief Business Officer** **4149 Liberty Canyon Road** **Agoura Hills, California 91301** **(805) 730-0360**	**Alan F. Denenberg** **Emily Roberts** **Davis Polk & Wardwell LLP** **1600 El Camino Real** **Menlo Park, California 94025** **(650) 752-2000**

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, 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. ☐

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.

EXPLANATORY NOTE

Pursuant to the applicable provisions of the Fixing America's Surface Transportation Act, we are omitting the unaudited interim financial statements of ACELYRIN, INC. for the nine months ended September 30, 2022 and 2021 in this draft confidential submission because they relate to historical periods that we believe will not be required to be included in this registration statement before distributing a preliminary prospectus to investors. Similarly, we are also omitting the unaudited pro forma condensed combined balance sheet as of September 30, 2022 and the unaudited condensed combined pro forma statement of operations for the nine months ended September 30, 2022 giving effect to the Acquisition (as defined in this registration statement), which closed on January 4, 2023, in this draft confidential submission. We intend to amend this registration statement to include all financial information required by Regulation S-X, including the audited financial statements of ValenzaBio, Inc. as of and for the year ended December 31, 2022, before distributing a preliminary prospectus to investors.

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The information in this preliminary prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell nor does it seek an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

PRELIMINARY PROSPECTUS (Subject to Completion)
Issued , 2023

Shares

ACELYRIN

Class A Common Stock

ACELYRIN, INC. is offering shares of its Class A Common Stock. This is our initial public offering, and no public market exists for our Class A Common Stock. We anticipate that the initial public offering price will be between $ and $ per share.

We intend to apply to list our Class A Common Stock on the Nasdaq Global Market (Nasdaq) under the symbol "XLRN." We believe that upon the completion of this offering, we will meet the standards for listing on Nasdaq, and the closing of this offering is contingent upon such listing.

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

We have two classes of common stock: the Class A Common Stock offered hereby and Class B Common Stock. The rights of the holders of Class A Common Stock and Class B Common Stock are identical, except with respect to voting and conversion. Each share of Class A Common Stock is entitled to one vote and is not convertible into any other class of our share capital. Shares of Class B Common Stock are non-voting, except as may be required by law. Each share of Class B Common Stock may be converted at any time into one share of Class A Common Stock at the option of its holder, subject to the beneficial ownership limitations provided for in our amended and restated certificate of incorporation. See the section titled "Description of Capital Stock" for more information on the rights of the holders of our Class A Common Stock and Class B Common Stock. We are offering Class A Common Stock in this offering. The Class B Common Stock will not be listed for trading on any securities exchange. Unless otherwise noted, all references in this prospectus to our "common stock" refer collectively to our Class A Common Stock and Class B Common Stock.

PRICE $ A SHARE

	Price to Public	*Underwriting Discounts and Commissions(1)*	*Proceeds to Acelyrin*
Per Share	*$*	*$*	*$*
Total	*$*	*$*	*$*

(1) See the section titled "Underwriters" for a description of the compensation payable to the underwriters.

We have granted the underwriters an option for a period of 30 days to purchase up to an additional shares of our Class A Common Stock solely to cover over-allotments, if any.

Investing in our Class A Common Stock involves a high degree of risk. See the section titled "Risk Factors" beginning on page 16 to read about factors you should consider before deciding to invest in shares of our Class A Common Stock.

Neither the Securities and Exchange Commission nor any other regulatory body has approved or disapproved of these securities or passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.

The underwriters expect to deliver the shares of Class A Common Stock to purchasers on , 2023.

Morgan Stanley *Jefferies* *Cowen* *Piper Sandler*

, 2023

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PROSPECTUS

Neither we nor the underwriters have authorized anyone to provide you any information or make any representations other than those contained in this prospectus or in any free writing prospectuses prepared by or on behalf of us or to which we have referred you. We and the underwriters take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. We and the underwriters are not making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information appearing in this prospectus or in any applicable free writing prospectus is current only as of its date, regardless of its time of delivery or any sale of shares of our Class A Common Stock. Our business, financial condition, results of operations and prospects may have changed since that date.

For investors outside of the United States: we have not, and the underwriters have not, 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 the United States. Persons outside of 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 Class A Common Stock and the distribution of this prospectus outside of 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 included elsewhere in this prospectus. This summary does not contain all of the information you should consider before investing in our Class A Common Stock. You should carefully read this entire prospectus, including the information in the sections titled "Risk Factors," "Special Note Regarding Forward-Looking Statements" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our audited financial statements and the related notes included elsewhere in this prospectus, before making an investment decision. Unless the context requires otherwise, references in this prospectus to "ACELYRIN," the "Company," "we," "us" and "our" refer to ACELYRIN, INC.

ACELYRIN, INC.

Overview

ACELYRIN is a late-stage clinical biopharma company focused on identifying, acquiring, and accelerating the development and commercialization of transformative medicines. We are driven by our sense of urgency to bring life-changing therapies to patients globally, a core value that we refer to as "courageous caring."

Our initial focus is on the treatment of diseases with pathology related to excess activation of the immune system, an area where our management and team bring industry-leading expertise. We acquired our portfolio of product candidates with the intent to develop and commercialize novel therapies that we believe provide the opportunity to offer clinically meaningful, differentiated benefits for patients by improving upon the efficacy and/or safety of existing therapeutics directed against established targets, such as currently marketed anti-interleukin (IL)-17A agents, or by targeting new modalities. In each case, our strategy is to identify candidates we believe are "diamonds in the rough," where, based on molecule characteristics, our collective experience and expertise, and the evolving scientific and medical understanding, we can establish a clinical development plan that tests our hypotheses as to what those benefits could mean for patients. Subsequently, we utilize the results from initial clinical trials and the learnings we obtain from emerging biology to expand the application of our candidates to other indications in which there are significant unmet needs.

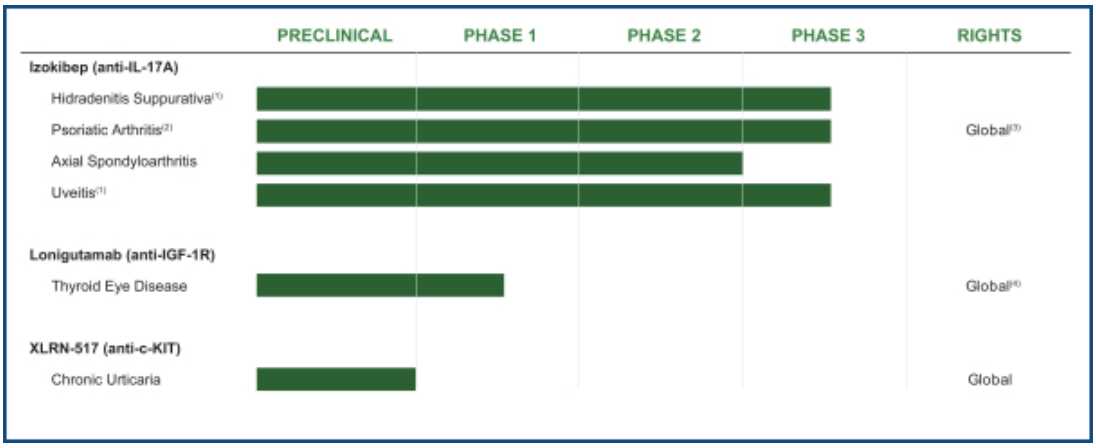
Our current portfolio consists of multiple clinical and preclinical stage product candidates being investigated across several indications and representing multi-billion-dollar opportunities in the aggregate.

Our Pipeline

Our lead product candidate is izokibep, a small protein therapeutic designed to inhibit IL-17A with higher potency through exponentially higher binding affinity and the potential for greater tissue penetration compared to traditional monoclonal antibodies due to its markedly smaller size.

We are also advancing lonigutamab, a humanized immunoglobulin G1 (IgG1) monoclonal antibody against insulin-like growth factor 1 receptor (IGF-1R). Lonigutamab has been shown to be markedly more potent than the currently marketed therapy for thyroid eye disease (TED) in both binding and functional laboratory assays.

In addition, we are developing XLRN-517, which is a fully human IgG1 monoclonal antibody targeting c-KIT. The inhibition of c-KIT reduces mast cell proliferation and activity in various allergy and inflammatory diseases. XLRN-517 is designed as a highly potent inhibitor (antagonism) of the c-KIT pathway, targeting mast cell proliferation and degranulation, without stimulating (agonism) mast cell degranulation. XLRN-517 has lower potential for immunogenicity relative to monoclonal antibodies that are not fully human.



(1) Phase 2b/3 trial in moderate-to-severe hidradenitis suppurativa (HS) and uveitis. Planned inclusion into registrational package for HS and non-infectious uveitis (as applicable) if granted orphan drug designation and following consultation with relevant heath authorities.
(2) Phase 2b/3 trial in psoriatic arthritis (PsA).
(3) Excludes development, commercialization and manufacturing rights in mainland China, Hong Kong, Macau, South Korea and Taiwan, and development rights in certain other Asia Pacific countries. We retain decision making authority for izokibep global development. See the section titled "Business—License and Collaboration Agreements" for further information.
(4) Worldwide rights to non-oncology indications. See the section titled "Business—License and Collaboration Agreements" for further information.

Our Team and Investors

Our company is led by Shao-Lee Lin, M.D., Ph.D., our Founder and Chief Executive Officer. Prior to founding our company, Dr. Lin was the first Chief Scientific Officer at Horizon Therapeutics plc, where she led research and development, including the development and approval of teprotumumab for the treatment of TED. Prior to Horizon, she held multiple positions at AbbVie Inc., most recently leading Therapeutic Areas, Development Excellence and International Development and initially as Vice President, Global Immunology and Renal Development. Prior to AbbVie, Dr. Lin served as Vice President, Inflammation and Respiratory Development at Gilead Sciences Inc. and served in various roles of increasing responsibility at Amgen Inc. Dr. Lin has been faculty as a Clinical Scholar at The Rockefeller University and adjunct faculty at the medical schools of Cornell University, The University of California, Los Angeles (UCLA), Stanford University and Northwestern University. Dr. Lin is joined by a team of veteran biopharma executives who together bring exceptional track records of identifying, acquiring, and then rapidly and robustly developing and commercializing medicines. These leaders were instrumental in achieving the first approvals, or expanded indications, for transformative therapies including Humira, Tepezza, Rinvoq, Skyrizi, Mavyret and Enbrel, that have provided clinically meaningful and differentiated benefit for patients. These therapies have subsequently become some of the most successful medicines within the biopharmaceutical industry.

Since our inception we have secured more than $550 million in committed capital, of which over $400 million has already been funded and $150 million will be funded, subject to certain conditions, by our Series C preferred stock investors if this offering is not completed by June 30, 2023.

Our Izokibep (Small Protein IL-17A Inhibitor) Program

Summary Overview of Izokibep

In numerous clinical trials, izokibep has demonstrated clinically meaningful and differentiated benefits and is currently in development for multiple immunological indications including HS, PsA, axial spondyloarthritis (AxSpA) and uveitis. Izokibep has been administered to more than 400 participants, including at doses up to 160 mg, and in some for up to three years. Izokibep has generally been well-tolerated with a safety profile consistent with that of the anti-IL-17A class as a whole.

Izokibep has demonstrated higher orders of clinical response in Part A of our Phase 2b/3 trial in HS, which we believe supports the potential to offer clinically meaningful, differentiated benefit to participants in this severe autoimmune condition where the hallmark of disease is skin abscesses, nodules, fistulae and scar tissue. Clinical responses in this open label portion of our ongoing Phase 2b/3 trial in HS were demonstrated at higher orders of Hidradenitis Suppurativa Clinical Response (HiSCR) where placebo response rates historically have been low-to-none. We have also shared results from a randomized, placebo-controlled Phase 2 trial of izokibep in PsA, which demonstrated differentiated clinical outcomes relative to available therapies. This was particularly evident in the difficult to treat entheseal tissues, where unchecked inflammation (enthesitis) is a marker of disease severity and is often associated with residual pain and physical dysfunction, negatively impacting quality of life. These results from our trials in HS and PsA offer two independent sets of clinical data supporting our hypothesis that izokibep could offer clinically meaningful, differentiated outcomes due to its high potency and small size, and therefore the potential to provide greater benefit to patients, especially in diseases with historically difficult to treat tissues where significant unmet needs remain.

As a result of our encouraging data in HS and PsA, we have prioritized development in these indications. For HS, in addition to the ongoing trial below, we plan to begin a second Phase 3 trial. For PsA, we accelerated into 2022 the initiation of a Phase 2b/3 trial evaluating a range of doses, including significantly higher doses than the Phase 2 trial based on our pharmacokinetics-pharmacodynamics (PK-PD) modeling that suggests increasing duration of treatment and higher doses could result in continued improvement of clinical outcomes. The trials we are currently enrolling with izokibep are a:

- Phase 2b/3 trial of izokibep in HS;
- Phase 2b/3 trial of izokibep in PsA; and
- Phase 2b/3 trial of izokibep in uveitis.

Additionally, we are planning to initiate two Phase 3 trials in AxSpA based on dosing data from the ongoing PsA Phase 2b/3 trial. Enthesitis is a key feature of AxSpA, and central to the progression of the disease. Therefore, we believe the benefits of izokibep on enthesitis demonstrated in PsA could be even more meaningful for patients with AxSpA.

We plan to seek orphan drug designation from the relevant regulatory authorities for both moderate-to-severe HS, as well as non-infectious uveitis. In each case, assuming this orphan designation is granted, and subject to discussions with the relevant regulatory authorities, we are conducting the ongoing Phase 2b/3 trials in these indications to enable inclusion in a future registrational package, potentially requiring only one confirmatory Phase 3 clinical trial for each indication.

Interleukin-17A, a Clinically Validated Target

Due to the central role of IL-17 in driving the expression of other proinflammatory cytokines and the recruitment of immune cells, down-regulating it with a biologic can lead to broad anti-inflammatory activity. The IL-17 family consists of at least six structurally similar cytokines, named IL-17A through IL-17F. Amongst them, IL-17A and IL-17F are known to drive inflammation and host defense by inducing secretion of proinflammatory cytokines, chemokines and antimicrobial peptides via IL-17 receptor A and receptor C.

While IL-17A inhibition alone has been clinically validated to reduce inflammation, with the approval of secukinumab and ixekizumab, IL-17F inhibition alone has been shown to have minimal effect. Additionally, IL-17A and IL-17F are both involved in mucosal immunity. Simultaneous blockade of IL-17A and IL-17F has been shown to be associated with dose-dependent increased risk of infection, especially fungal infections.

Immune dysregulation driven by IL-17A has been identified as a driver of inflammation in many autoimmune and inflammatory diseases. These include PsA, HS, AxSpA, uveitis, and psoriasis (PsO). In each of these diseases, elevated levels of IL-17A are found in patient's sera, and in skin diseases, such as PsO, at lesion sites.

Izokibep is Highly Differentiated from Monoclonal Antibodies

Izokibep is a small protein therapeutic designed to bind the homodimeric IL-17A molecule with high potency. In contrast to conventional monoclonal antibodies which are multi-subunit proteins, izokibep is much smaller – approximately one-tenth the size of a traditional monoclonal antibody – containing two IL-17A binding domains and an albumin binding domain that results in improved PK properties.

By virtue of its structure and size, we believe izokibep has several key potential advantages over traditional monoclonal antibodies:

- **Enhanced potency**. Izokibep binds both subunits of the IL-17A dimer simultaneously, resulting in complete blockade of IL-17 signaling in preclinical studies. Izokibep is highly potent with a dissociation constant (K_D) of 0.3 pM to human IL-17A, compared to currently U.S. Food and Drug Administration (FDA)-approved anti-IL-17A agents secukinumab, which has a K_D of 200 pM, and ixekizumab, which has a K_D of 1.8 pM.
- **Albumin-binding domain provides half-life extension and improved tissue exposure**. The albumin-binding domain increases the plasma half-life of izokibep and enhances its ability to target sites of inflammation.
- **Smaller size improves tissue penetration**. Izokibep is approximately one-tenth the size of a monoclonal antibody, enabling the potential to reach poorly vascularized tissues that are difficult to access with traditional monoclonal antibodies. In murine skin, izokibep demonstrated greater exposure, increasing over time, compared to secukinumab.
- **Potential to deliver higher exposures more conveniently**. The lower molecular weight of izokibep (18.6 kDa) compared to traditional monoclonal antibodies (~150 kDa) means that there are more izokibep drug molecules, and potentially more potent molecules, in the same injection volume. As a result, we believe izokibep can deliver in a single subcutaneous injection exposure levels that monoclonal antibodies require IV infusion to deliver.

Izokibep for the Treatment of Moderate-to-Severe HS

HS is a chronic, scarring, painful and debilitating inflammatory skin disease characterized by occlusion of hair follicles in sweat glands. These inflamed areas are often colonized by bacteria leading to further inflammation and initiating a chronic cycle of inflammation, healing, and scarring. Inflammation can lead to inflamed nodules and abscesses due to draining skin tunnels and bands of severe scarring. HS typically occurs in areas with high concentrations of sweat glands and where skin folds touch or rub together such as the arm pit, groin, perianal region and under the breast. Based on market research conducted for us by Skysis, a member of Fishawack Health (Skysis), the total market globally for the treatment of HS in 2022 was approximately $1.2 billion and is expected to grow to approximately $2.9 billion by 2030.

High serum levels of IL-17A have been found in HS patients and these levels are correlated with the severity of inflammation. The fundamental role of high levels of IL-17A in bridging the innate and adaptive immune system, and in stimulating the expression of inflammatory cytokines, is well recognized and has driven clinical trials with anti-IL-17 biologic agents in HS. Recent positive results from Phase 3 trials of secukinumab and bimekizumab in HS validated the therapeutic potential of IL-17 inhibition in this disease. In January 2023, we announced that at Week 12 izokibep achieved higher orders of HiSCR in Part A of our ongoing Phase 2b/3 trial in HS, which we believe supports the potential to offer clinically meaningful, differentiated benefit to participants in this severe autoimmune condition where the hallmark of disease is skin abscesses, nodules, fistulae and scar tissue. Clinical responses in this open label portion of our ongoing Phase 2b/3 trial in HS were demonstrated at higher orders of HiSCR, where placebo response rates historically have been low to none. Furthermore, safety results were consistent with previous trials of izokibep as well as the anti-IL-17A class as a whole, with no increased risk of infection, including candida. Data from Part A of this trial will be presented at a future scientific meeting.

Izokibep for the Treatment of PsA

PsA is a chronic immune-mediated inflammatory disease characterized by both joint inflammation and skin lesions consistent with PsO. It is estimated that approximately 30% of the 125 million people living with PsO worldwide will also develop PsA over time. We have presented results of our placebo-controlled double-blind Phase 2 trial of izokibep in PsA at the 2022 European Alliance of Associations for Rheumatology (EULAR) Congress and the 2022 American College of Rheumatology (ACR) conference. Based on market research conducted for us by Skysis, the total market globally for the treatment of PsA in 2022 was approximately $8.8 billion and is expected to grow to approximately $17.8 billion by 2030.

We believe the Phase 2 trial results demonstrate izokibep has the potential to provide clinically meaningful, differentiated benefits in the treatment of PsA over existing therapies.

In the trial, both the 40 mg and 80 mg doses of izokibep demonstrated significant improvements compared to placebo. Results for the 80 mg dose in particular exceeded the joint and PsO responses of approved therapies treating moderate-to-severe PsA, and resolution of enthesitis was markedly differentiated from historically reported response rates.

Our ultimate goal is to improve quality of life for patients. To that end, we assessed multiple measures of participant-reported outcomes as part of the trial, including the Psoriatic Arthritis Impact of Disease (PsAID) questionnaire, developed and validated by GRAPPA (the Group for Research and Assessment of Psoriatic Arthritis), a preeminent group of rheumatology thought-leaders.

The PsAID results for the overall population in this trial revealed statistically significant, clinically meaningful and dose-dependent improvements in all quality of life sub-domains of the PsAID including pain, sleep disturbance and functional capacity. Furthermore, we observed that participants with enthesitis at baseline reported even greater improvement in quality of life.

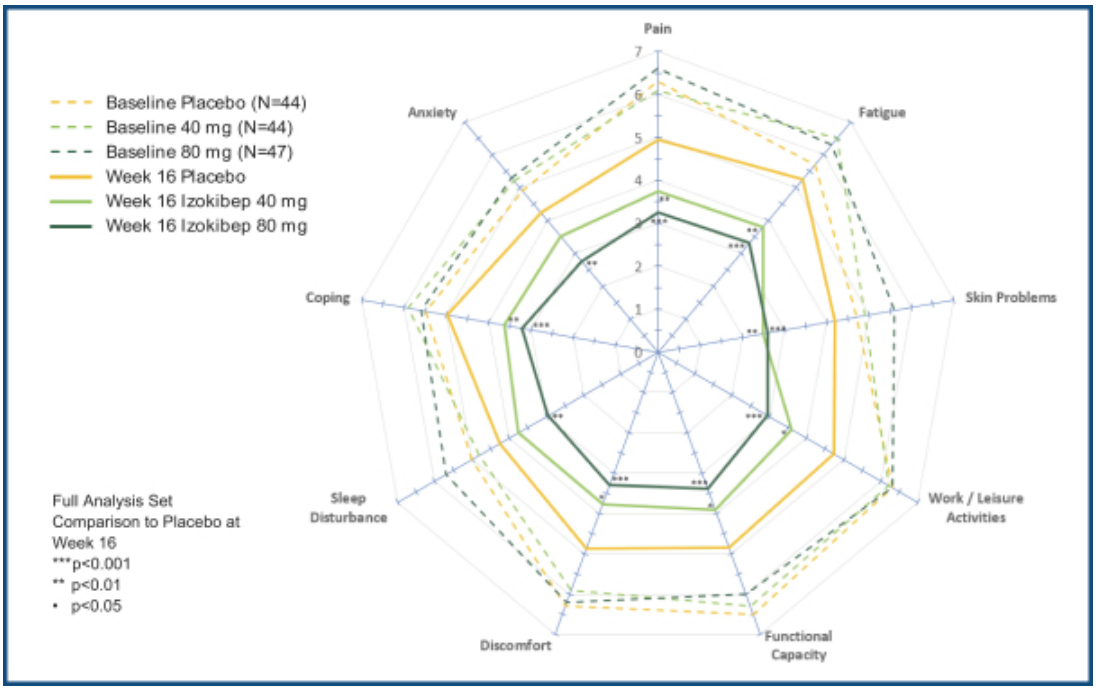


Figure A. Izokibep led to a dose-dependent response across the spectrum of participant reported outcomes as measured by PsAID. In this radar plot, lower scores closer to the center of the figure represent better outcomes. Each spoke represents a participant reported outcome from the PsAID. Changes in the magnitude of the scores of individual outcomes are represented by the distance from the center point.

In this Phase 2 trial izokibep was well-tolerated – in line with previous trials of izokibep and the IL-17A class as whole – and no treatment-related serious adverse events (SAEs) were reported/observed across all cohorts. The most common adverse event (AE) was injection site reactions. Injection site reactions were mild-to-moderate, the size of a quarter to half dollar, and typically presented within the first three injections, after which they generally did not occur.

Encouraged by the Phase 2 trial data, we are enrolling a Phase 2b/3 trial of izokibep in PsA with 160 mg delivered subcutaneously once weekly (QW) or once every two weeks (Q2W), or 80 mg every four weeks (Q4W). Our modeling of the Phase 2 trial data suggests increasing duration of treatment and higher doses will each result in continued improved outcomes across clinically validated PsA endpoints. An independent interim analysis from this Phase 2b/3 trial will inform the final dose selection for the planned second Phase 3 trial.

Izokibep for the Treatment of AxSpA

AxSpA is a chronic inflammatory disease predominantly affecting the axial skeleton, primarily the spine from the pelvis to the neck, although it often affects peripheral joints including knees, hips, and shoulders. There are an estimated 2.5 million patients with AxSpA in the United States and Europe, with more than 150,000 of such patients currently treated with biologics. Based on market research conducted for us by Skysis, the total market globally for the treatment of AxSpA in 2022 was approximately $5.1 billion and is expected to grow to greater than $6.8 billion by 2030.

Enthesitis is central to the pathology of AxSpA and the enthesitis resolution rates observed in our Phase 2 trial of izokibep in PsA have strengthened our hypothesis for our AxSpA program. Once the optimal dose is selected in PsA, we intend to initiate two Phase 3 double-blind, placebo-controlled trials in AxSpA with that chosen dose.

Izokibep for the Treatment of Uveitis

Uveitis is an inflammatory disease of the eye that sometimes arises in association with other immune-related diseases. More than 90% of uveitis cases have been reported to be non-infectious, chronic and recurrent in nature with a prevalence in the United States of 121 cases per 100,000. Based on market research conducted for us by Skysis, the total market globally for the treatment of non-infectious uveitis in 2022 was approximately $390 million and is expected to grow to greater than $790 million by 2030.

We are currently conducting a Phase 2b/3 trial of izokibep in non-infectious uveitis.

Safety Profile of Izokibep

Izokibep has been administered to more than 400 participants, including at doses up to 160 mg, and in some for up to three years. Izokibep has generally been well-tolerated with a safety profile consistent with that of the anti-IL-17A class as a whole. Based on data from our two completed clinical trials of izokibep, as well as the Week 16 data from our Phase 2 trial in PsA, we generally observed one common AE, which was injection site reactions. Injection site reactions were mild-to-moderate, the size of a quarter to half dollar, and typically presented within the first three injections, after which they generally did not occur.

Our Lonigutamab (IGF-1R Monoclonal Antibody) Program

Lonigutamab, our second development program, is a subcutaneously delivered humanized IgG1 monoclonal antibody against IGF-1R for the treatment of TED. Lonigutamab has *in vitro* potency up to 75-fold higher than that of teprotumumab and targets a distinct epitope of IGF-1R. Our preclinical studies demonstrated that, when biopsy samples from TED participants were treated with equimolar amounts of teprotumumab and lonigutamab, lonigutamab had greater inhibition of IGF-1R signaling as measured by IGF-1 stimulated hyaluronan production. Furthermore, we believe that the characteristics of lonigutamab that enable subcutaneous delivery also allows for reduction of maximum serum concentration (C_{max}) incurred with current intravenous (IV) therapies. Decreasing C_{max} may lessen breach of the blood labyrinth barrier and limit IGF-1R inhibition in the neural tissues of the inner ear. IGF-1R is neuroprotective to cells of the inner ear and serves to repair the cellular damage that occurs by various processes including age-associated degeneration. In addition to the potential benefit of decreasing the side effect of hearing impairment, these characteristics of lonigutamab enable evaluation for greater depth and durability of clinical response. The multiple ascending dose (MAD) portion of our Phase 1 trial in TED is currently recruiting.

Our XLRN-517 (c-KIT Monoclonal Antibody) Program

We are also developing XLRN-517, a monoclonal antibody designed to target a distinct epitope of c-KIT, the inhibition of which can reduce mast cell proliferation and activity in various allergy and inflammatory diseases. Monoclonal antibody therapies have demonstrated lower risk of off target toxicities compared to small molecule therapeutics.

XLRN-517 has higher affinity and is more potent across a number of *in vitro* assays than other antibodies targeting this pathway. We believe XLRN-517 has the potential to address multiple indications beyond chronic urticaria, in diseases where mast cells appear to be a key part of the pathogenesis. Other potential indications where mast cells may play a central role include prurigo nodularis, bullous pemphigoid and eosinophilic esophagitis.

Our Strategy

Our vision is to build a leading integrated biopharma company focused on delivering transformative medicines to patients. Immunology is an area of deep core expertise throughout the organization, and therefore is our area of initial focus. Our mission is to identify, acquire, and accelerate the development and commercialization of medicines that we believe have the potential to offer clinically meaningful, differentiated benefits to patients. We intend to achieve that goal by implementing the following strategies:

- Maximize the "pipeline-in-a-program" potential of izokibep.
- Advance lonigutamab for the treatment of TED.
- Advance earlier stage product candidates into clinical development.
- Diversify our portfolio with new product candidates.
- Evaluate strategic collaborations.
- Build our operational and commercial capabilities for supplying and marketing our products, if approved, in key markets.

ValenzaBio Acquisition

We acquired ValenzaBio, Inc. (ValenzaBio) in an all stock transaction on January 4, 2023 (the Acquisition). In connection with the Acquisition, we issued an aggregate of 37,242,709 shares of our Class A Common Stock to ValenzaBio stockholders and assumed options of certain ValenzaBio optionholders which are now exercisable for an aggregate of 2,464,653 shares of our Class A Common Stock. The Acquisition added clinical and preclinical development programs to our pipeline, including lonigutamab and XLRN-517 with mechanisms and targeted disease states for which our team has significant relevant experience.

Risks Related to Our Business

Investing in our Class A Common Stock involves substantial risk. The risks are discussed more fully in the section titled "Risk Factors" immediately following this Prospectus Summary. These risks include, but are not limited to the following:

- We are a clinical stage biopharma company with a limited operating history and no products approved for commercial sale.
- Preclinical and clinical development involves a lengthy and expensive process, with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our current product candidates or any future product candidates.

- We will require substantial additional financing to achieve our goals and failure to obtain additional capital when needed, or on acceptable terms to us, could cause us to delay, limit, reduce, or terminate our product development or future commercialization efforts.
- Our clinical trials may reveal significant adverse events not seen in our preclinical studies or prior clinical trials and may result in a safety or tolerability profile that could delay or prevent regulatory approval or market acceptance of izokibep, lonigutamab, any of our other product candidates or any future product candidates.
- We face competition from entities that have made substantial investments into the rapid development of novel treatments for immunological indications, including large and specialty pharmaceutical and biotechnology companies, many of which already have approved therapies in our current indications.
- 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 planned Phase 3 clinical trials of izokibep for moderate-to-severe HS as well as non-infectious uveitis, even if successfully completed, may not be sufficient for approval of izokibep for the applicable indication.
- Even if we receive regulatory approval for any of our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal. We may also be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.
- We may have conflicts with our current or future licensors or collaborators that could delay or prevent the development or commercialization of our product candidates.
- We recently acquired ValenzaBio, and we expect to engage in strategic transactions in the future, which could impact our liquidity, increase our expenses and present significant distractions to our management.
- If we are unable to obtain and maintain sufficient intellectual property protection for our product candidates and any future product candidates we may develop, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors or other third parties could develop and commercialize products similar or identical to ours, and our ability to successfully develop and commercialize our product candidates may be adversely affected.
- We have identified material weaknesses in our internal control over financial reporting. If we fail to remediate these material weaknesses, or if we experience additional material weaknesses in the future or otherwise fail to maintain effective internal control over financial reporting in the future, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our Class A Common Stock.

Corporate Information

We were founded in July 2020 as a Delaware corporation. Our principal executive offices are located at 4149 Liberty Canyon Road, Agoura Hills, California, 91301 and our telephone number is (805) 730-0360. Following the Acquisition, WH2, LLC is our sole wholly owned subsidiary. Our website address is www.acelyrin.com. Information contained in, or accessible through, our website is not a part of this prospectus and the inclusion of our website address in this prospectus is only an inactive textual reference.

Trademarks and Service Marks

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 TM 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

We qualify as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, as amended (JOBS Act). As an emerging growth company, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies. These provisions include:

- being permitted to present 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 in this prospectus;
- reduced disclosure about our executive compensation arrangements;
- not being required to hold advisory votes on executive compensation or to obtain stockholder approval of any golden parachute arrangements not previously approved;
- an exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act of 2002; and
- an exemption from compliance with the requirements of the Public Company Accounting Oversight Board regarding the communication of critical audit matters in the auditor's report on the financial statements.

We may take advantage of these exemptions for up to five years or such earlier time that we are no longer an "emerging growth company." We would cease to be an emerging growth company on the date that is the earliest of (i) the last day of the fiscal year in which we have total annual gross revenue of $1.24 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of the date of the completion of this offering; (iii) the date on which we have issued more than $1.0 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the Securities and Exchange Commission (SEC). We may choose to take advantage of some but not all of these exemptions. We have taken advantage of reduced reporting requirements in this prospectus. Accordingly, the information contained herein may be different from the information you receive from other public companies in which you hold stock. Additionally, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this exemption and, therefore, while we are an emerging growth company we will not be subject to new or revised accounting standards at the same time that they become applicable to other public companies that are not emerging growth companies. As a result of this election, our financial statements may not be comparable to those of other public companies that comply with new or revised accounting pronouncements as of public company effective dates. We may choose to early adopt any new or revised accounting standards whenever such early adoption is permitted for private companies.

The Offering

Class A Common Stock offered by us	shares.
Option to purchase additional shares of Class A Common Stock	We have granted the underwriters an option for a period of 30 days to purchase up to an additional shares of our Class A Common Stock at the initial public offering price, less underwriting discounts and commissions.
Class A Common Stock to be outstanding immediately after this offering	shares (or shares if the underwriters exercise their option to purchase additional shares of our Class A Common Stock in full).
Class B Common Stock to be outstanding immediately after this offering	None.
Use of proceeds	We estimate that the net proceeds from this offering will be approximately $ million (or approximately $ million if the underwriters exercise their option to purchase additional shares of our Class A Common Stock in full), based on the assumed initial public offering price of $ per share, which is the midpoint of the estimated 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. We intend to use the net proceeds from this offering, together with our existing cash as follows: (i) to advance the clinical development of izokibep through ; (ii) to advance the clinical development of lonigutamab through ; (iii) to fund our other development efforts, including XLRN-517; and (iv) for general corporate purposes, including working capital, operating expenses and other capital expenditures. See the section titled “Use of Proceeds” for additional information.
Voting rights	We have two classes of common stock: the Class A Common Stock offered hereby and Class B Common Stock. Each holder of our Class A Common Stock is entitled to one vote for each share on all matters submitted to a vote of the stockholders, including the election of directors, and holders of our Class B Common Stock are not entitled to any votes per share. Shares of Class B Common Stock are convertible into shares of Class A Common Stock at any time, subject to the Beneficial Ownership Limitation (as defined below). For a description of the rights of the Class A Common Stock and Class B Common Stock and the

	Beneficial Ownership Limitation, see the section titled "Description of Capital Stock—Class A Common Stock and Class B Common Stock."
Risk factors	See the section titled "Risk Factors" and other information included in this prospectus for a discussion of factors you should consider carefully before deciding to invest in our Class A Common Stock.
Proposed Nasdaq Global Market trading symbol	"XLRN"

The number of shares of our Class A Common Stock and Class B Common Stock to be outstanding after this offering is based on shares of our Class A Common Stock outstanding as of March 31, 2023 (including shares of unvested restricted stock subject to a repurchase option by us, and giving effect to (i) the automatic conversion of shares of our redeemable convertible preferred stock into an equivalent number of shares of our Class A Common Stock, which will occur immediately prior to the closing of this offering, and (ii) shares of our Class A Common Stock issuable upon vesting and settlement of restricted stock units (RSUs) at the completion of this offering) and no shares of Class B Common Stock outstanding.

The number of shares of Class A Common Stock and Class B Common Stock to be outstanding after this offering excludes:

- shares of our Class A Common Stock issuable upon the exercise of outstanding stock options as of March 31, 2023 under our 2020 Stock Option and Grant Plan (2020 Plan), with a weighted-average exercise price of $ per share;
- shares of our Class A Common Stock issuable upon the exercise of outstanding stock options granted subsequent to March 31, 2023 under our 2020 Plan, with a weighted-average exercise price of $ per share;
- shares of our Class A Common Stock issuable upon the exercise of outstanding stock options assumed in connection with the Acquisition, with a weighted-average exercise price of $ per share;
- shares of our Class A Common Stock issuable upon vesting and settlement of RSUs outstanding as of March 31, 2023, net of RSUs, which will vest upon the completion of this offering;
- shares of our Class A Common Stock reserved for future issuance under our 2023 Equity Incentive Plan (2023 Plan), which will become effective once the registration statement of which this prospectus forms a part is declared effective, including new shares plus the number of shares (not to exceed shares) that (i) remain available for grant of future awards under the 2020 Plan and will cease to be available for issuance under the 2020 Plan at the time our 2023 Plan becomes effective in connection with this offering, and (ii) are underlying outstanding stock awards granted under our 2020 Plan, that expire or are repurchased, forfeited, cancelled or withheld, as well as any future automatic annual increases in the number of shares of Class A Common Stock reserved for issuance under our 2023 Plan and, as more fully described in the section titled "Executive Compensation—Equity Benefit Plans;" and
- shares of our Class A Common Stock reserved for issuance under our 2023 Employee Stock Purchase Plan (ESPP), which will become effective once the registration statement of which this prospectus forms a part is declared effective, as well as any future automatic annual increases in the number of shares of Class A Common Stock reserved for future issuance under our ESPP, as more fully described in the section titled "Executive Compensation—Equity Benefit Plans."

Unless otherwise indicated, this prospectus assumes or gives effect to:

- a 1-for- reverse stock split of our Class A Common Stock effected on , 2023;
- the automatic conversion of outstanding shares of our redeemable convertible preferred stock into an equivalent number of shares of our Class A Common Stock, which will occur immediately prior to the closing of this offering;
- no exercise of outstanding options or settlement of RSUs subsequent to March 31, 2023;
- no repurchases by us of unvested restricted stock subsequent to March 31, 2023;
- no exercise by the underwriters of their option to purchase up to additional shares of Class A Common Stock from us in this offering;
- no shares of Class B Common Stock outstanding as of the date of this offering;
- an assumed initial public offering price of $ per share, which is the midpoint of the estimated price range set forth on the cover page of this prospectus; and
- the filing and effectiveness of our amended and restated certificate of incorporation to be in effect immediately prior to the closing of this offering and the adoption of our amended and restated bylaws upon the closing of this offering.

Summary Financial Data

The following tables set forth our summary financial data for the periods and as of the dates indicated. The following summary statements of operations data for the years ended December 31, 2021 and 2022 have been derived from our audited financial statements included elsewhere in this prospectus. The following summary interim condensed consolidated statements of operations data for the three months ended March 31, 2022 and 2023, and the summary interim condensed consolidated balance sheet data as of March 31, 2023, have been derived from our unaudited interim condensed consolidated financial statements included elsewhere in this prospectus. Our audited financial statements and unaudited interim condensed consolidated financial statements included elsewhere in this prospectus have been prepared in accordance with U.S. generally accepted accounting principles (U.S. GAAP). Our unaudited interim condensed consolidated financial statements were prepared on a basis consistent with our audited financial statements and include, in our opinion, all adjustments of a normal and recurring nature that are necessary for the fair statement of the financial information set forth in those statements included elsewhere in this prospectus. Our historical results are not necessarily indicative of the results that may be expected for any period in the future and results for the three months ended March 31, 2023 are not necessarily indicative of results to be expected for the year ending December 31, 2023. You should read the following summary financial data together with the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our audited financial statements and unaudited interim condensed consolidated financial statements and the related notes included elsewhere in this prospectus. The summary financial data included in this section are not intended to replace the financial statements and the related notes included elsewhere in this prospectus.

	Year Ended December 31,		Three Months Ended March 31,	
	2021	2022	2022	2023
	(in thousands, except share and per share data)			
Statements of Operations Data:				
Operating expenses:				
Research and development	$ 38,230	$	$	$
General and administrative	3,564			
Total operating expenses	41,794			
Loss from operations	(41,794)			
Other income (expense), net	(45)			
Net loss	$ (41,839)	$	$	$
Net loss per share attributable to common stockholders, basic and diluted[1]	$ (30.86)	$	$	$
Weighted-average common shares outstanding, basic and diluted[1]	1,355,553			
Pro forma net loss per share attributable to common stockholders, basic and diluted (unaudited)[2]		$		$
Pro forma weighted-average common shares outstanding, basic and diluted (unaudited)[2]				

(1) See Note 9 to our audited financial statements and Note to our unaudited interim condensed consolidated financial statements included elsewhere in this prospectus for details on the calculation of basic and diluted net loss per share attributable to common stockholders.

(2) The unaudited pro forma basic and diluted net loss per share attributable to common stockholders gives effect to (i) the automatic conversion of outstanding shares of our redeemable convertible preferred stock as of March 31, 2023 into an equivalent number of shares of our Class A Common Stock, as if such conversion had occurred on January 1, 2022, and (ii) shares of our Class A Common Stock issuable upon the vesting and settlement of RSUs that will vest upon the completion of this offering, and is calculated by dividing the pro forma net loss attributable to common stockholders by the pro forma weighted-average common shares outstanding for the period. Unaudited pro forma net loss attributable to common stockholders is the same as the amount of net loss attributable to common stockholders for each period presented. Unaudited pro forma basic and diluted net loss per share attributable to common stockholders does not include the effect of the shares of our Class A Common Stock expected to be sold in this offering.

	As of March 31, 2023		
	Actual	Pro Forma[1]	Pro Forma As Adjusted[2][3]
		(in thousands)	
Balance Sheet Data:			
Cash	$	$	$
Working capital[4]			
Total assets			
Total liabilities			
Redeemable convertible preferred stock			
Accumulated deficit			
Total stockholders' equity (deficit)			

(1) The pro forma balance sheet data gives effect to (i) the automatic conversion of outstanding shares of our redeemable convertible preferred stock into an equivalent number of shares of our Class A Common Stock, which will occur immediately prior to the closing of this offering, (ii) the vesting of shares of our Class A Common Stock issuable upon vesting and settlement of RSUs upon the completion of this offering and (iii) the filing and effectiveness of our amended and restated certificate of incorporation to be in effect immediately prior to the closing of this offering.

(2) The pro forma as adjusted 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 our Class A Common Stock in this offering at the assumed initial public offering price of $ per share, which is the midpoint of the estimated 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) The pro forma as adjusted information is illustrative only and will depend on the actual initial public offering price and other terms of this offering determined at pricing. Each $1.00 increase (decrease) in the assumed initial public offering price of $ per share, which is the midpoint of the estimated price range set forth on the cover page of this prospectus, would increase (decrease), each of our cash, working capital, total assets and total stockholders' equity (deficit) by $ 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 (decrease) of 1,000,000 shares in the number of shares of Class A Common Stock offered by us would increase (decrease) each of our cash, working capital, total assets, and total stockholders' equity (deficit) by $ million, assuming the assumed initial offering price per share remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

(4) Working capital is defined as current assets less current liabilities.

RISK FACTORS

Investing in our Class A Common Stock involves a high degree of risk. Before deciding to invest in shares of our Class A Common Stock, you should carefully consider the risks described below, together with the other information contained in this prospectus, including in the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and in our audited financial statements and the related notes included elsewhere in this prospectus. We cannot assure you that any of the events discussed below will not occur. These events could adversely impact our business, financial condition, results of operations and prospects. If that were to happen, the trading price of our Class A Common Stock could decline, and you could lose all or part of your investment.

Risks Related to Our Financial Position and Need for Capital

We are a clinical stage biopharma company with a limited operating history and no products approved for commercial sale.

We are a clinical stage biopharma company with a limited operating history on which to base your investment decision. We have no product candidates approved for commercial sale and have not generated any revenue. Biopharmaceutical product development is a highly speculative undertaking. It entails substantial upfront capital expenditures and significant risk that any product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval or become commercially viable.

Our lead product candidate is izokibep, an IL-17A inhibitor. We are currently conducting Phase 2b/3 trials of izokibep in each of HS, PsA and uveitis. For HS, in addition to the ongoing Phase 2b/3 trial, we plan to initiate second Phase 3 trial. We are also planning to initiate two Phase 3 trials in AxSpA based on dosing data from the ongoing PsA Phase 2b/3 trial. In addition, we are advancing lonigutamab, an IGF-1R inhibitor, currently in the MAD portion of a Phase 1 trial in TED. We are also developing XLRN-517, a monoclonal antibody targeting c-KIT, for the treatment of chronic urticaria. We have and will continue to incur significant development and other expenses related to our clinical development and ongoing operations. For the years ended December 31, 2021 and December 31, 2022, our net losses were approximately $41.8 million and $ million, respectively. As of December 31, 2022, we had an accumulated deficit of approximately $ million. Substantially all of our losses have resulted from expenses incurred in connection with the acquisition and development of our pipeline and from general and administrative costs associated with our operations. We expect to incur significant losses for the foreseeable future, and we expect these losses to increase as we continue our development of our product candidates.

We anticipate that our expenses will increase substantially if, and as, we:

- conduct further clinical trials for izokibep, lonigutamab, XLRN-517 and other programs;
- identify additional product candidates and acquire rights from third parties to those product candidates through licenses or other acquisitions, and conduct development activities, including preclinical studies and clinical trials;
- procure the manufacturing of preclinical, clinical and commercial supply of our current and future product candidates;
- seek regulatory approvals for our product candidates or any future product candidates;
- commercialize our current product candidates or any future product candidates, if approved;
- take steps toward our goal of being an integrated biopharma company capable of supporting commercial activities, including establishing sales, marketing and distribution infrastructure;
- attract, hire and retain qualified clinical, scientific, operations and management personnel;
- add and maintain operational, financial and information management systems;

- protect, maintain, enforce and defend our rights in our intellectual property portfolio;
- defend against third-party interference, infringement and other intellectual property claims, if any;
- address any competing therapies and market developments;
- experience any delays in our preclinical studies or clinical trials and regulatory approval for our product candidates due to the impacts of the COVID-19 pandemic, macroeconomic conditions or geopolitical conflicts; and
- incur additional costs associated with operating as a public company following the completion of this offering.

Even if we succeed in commercializing one or more product candidates, we expect to incur substantial development costs and other expenditures to develop and market additional product candidates. We may also encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue or raise additional capital. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and our working capital.

Preclinical and clinical development involves a lengthy and expensive process, with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our current product candidates or any future product candidates.

All of our product candidates are either in preclinical or clinical development and their risk of failure is high. It is impossible to predict when or if any of our product candidates will receive regulatory approval. To obtain the requisite regulatory approvals to commercialize any product candidates, we must demonstrate through extensive preclinical studies and lengthy, complex and expensive clinical trials that our product candidates are safe and effective in humans. Clinical testing can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. 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. We may be unable to establish clinical endpoints that applicable regulatory authorities would consider clinically meaningful, and a clinical trial can fail at any stage of testing. Differences in trial design between early-stage clinical trials and later-stage clinical trials make it difficult to extrapolate the results of earlier clinical trials to later clinical trials. Moreover, clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in clinical trials have nonetheless failed to obtain marketing approval of such product candidates. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unfavorable safety profiles, notwithstanding promising results in earlier trials. There is typically a high rate of failure of product candidates proceeding through clinical trials. Most product candidates that commence clinical trials are never approved as products and there can be no assurance that any of our current or future clinical trials will ultimately be successful or support the approval of our current or any future product candidates.

Commencing any future clinical trials is subject to finalizing the trial design and submitting an application to the FDA or a similar foreign regulatory authority. Even after we make our submissions, the FDA or other regulatory authorities could disagree that we have satisfied their requirements to commence our clinical trials or disagree with our study design, which may require us to complete additional trials or amend our protocols or impose stricter conditions on the commencement of clinical trials.

We expect to continue to rely in part on our collaborators, contract research organizations (CROs) and clinical trial sites to ensure the proper and timely conduct of our clinical trials, including the participant enrollment process, and we have limited influence over their performance. We or our collaborators may experience delays in initiating or completing clinical trials due to unforeseen events or otherwise, that could

delay or prevent our ability to receive marketing approval or commercialize our current and any future product candidates, including:

- regulators, such as the FDA or comparable foreign regulatory agencies, Institutional Review Boards (IRBs), or ethics committees may not authorize us or our investigators to commence or conduct a clinical trial at a prospective trial site, or amend trial protocols, or regulators may require that we modify or amend our clinical trial protocols;
- we may experience delays in reaching, or fail to reach, agreement on acceptable terms with existing and prospective trial sites and CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- clinical trial sites deviating from trial protocol or dropping out of a trial;
- clinical trials of our product candidates may fail to show safety, tolerability or efficacy, or may produce negative or inconclusive results, or may otherwise fail to improve on the existing standard of care, and we may decide, or regulators may require us, to conduct additional clinical trials or we may decide to abandon product development programs;
- apparent improvement in placebo-treated patients, which could lead to inconclusive results from our clinical trials;
- the number of participants required for clinical trials may be larger than we anticipate, enrollment in clinical trials may be slower than we anticipate or participants may drop out of clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate;
- the cost of clinical trials of any of our product candidates may be 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 submission of a Biologic License Application (BLA);
- the quality or quantity of data relating to our product candidates or other materials necessary to conduct our clinical trials may be inadequate to initiate or complete a given clinical trial;
- reports from clinical testing of other therapies may raise safety, tolerability or efficacy concerns about our product candidates;
- our failure to establish an appropriate safety or tolerability profile for a product candidate based on preclinical or clinical data for such product candidate as well as data emerging from other therapies in the same class as our product candidate; and
- the FDA, European Medicines Agency (EMA) or other regulatory authorities may require us to submit additional data such as long-term toxicology studies, or impose other requirements before permitting us to initiate a clinical trial.

Participant enrollment, a significant factor in the timing of clinical trials, is affected by many conditions including the size and nature of the patient population, the number and location of clinical sites we enroll, the proximity of participants to clinical sites, the eligibility and exclusion criteria for the trial, the design of the clinical trial, the inability to obtain and maintain participant consents, the risk that enrolled participants will drop out before completion, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs or biologics that may be approved for the indications being investigated by us. Risks related to patient enrollment are heightened in longer clinical trials, including the 52-week trial period contemplated by our ongoing Phase 2b/3 clinical trial of izokibep in PsA. In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same areas as our product candidates, and this competition will reduce the number and types of participants available to us, because some participants who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors, or to use currently marketed therapies. 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 participants who are available for our clinical trials at such clinical trial sites. Additionally, participants, including participants in any control groups, may withdraw from the clinical trial if they are not experiencing improvement in their underlying disease or condition. Additionally, we could encounter delays if treating clinicians encounter unresolved ethical issues associated with enrolling participants in clinical trials of our product candidates in lieu of prescribing existing treatments that have established safety and efficacy profiles.

Withdrawal of participants from our clinical trials may compromise the quality of our data. Even if we are able to enroll a sufficient number of participants in our clinical trials, delays in enrollment or small population size may result in increased costs or may affect the timing or outcome of our clinical trials. Any of these conditions may negatively impact our ability to complete such trials or include results from such trials in regulatory submissions, which could adversely affect our ability to advance the development of our product candidates.

We could also encounter delays if a clinical trial is suspended, put on clinical hold or terminated by us, the IRBs of the institutions in which such trials are being conducted, the FDA, EMA or other regulatory authorities, or if a clinical trial is recommended for suspension or termination by the Data Safety Monitoring Board (DSMB) for such trial. A suspension or termination may be imposed due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, failure by our CROs to perform in accordance with the Good Clinical Practice (GCP) requirements, or applicable regulatory guidelines in other countries, inspection of the clinical trial operations or trial site by the FDA, EMA 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 or treatment, failure to establish or achieve clinically meaningful trial endpoints, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. Clinical trials may also be delayed or terminated as a result of ambiguous or negative interim results. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. Further, the FDA, EMA or other regulatory authorities may disagree with our clinical trial design and our interpretation of data from clinical trials, or may change the requirements for approval even after they have reviewed and commented on the design for our clinical trials.

We may also, in the future, conduct preclinical and clinical research in collaboration with other academic, pharmaceutical and biotechnology entities in which we combine our development efforts 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 may increase our future costs and expenses.

Our product development costs will increase if we experience delays in clinical testing or marketing approvals. We do not know whether any of our clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates and may allow our competitors to bring products to market before we do, potentially impairing our ability to successfully commercialize our product candidates. Any delays or increase in costs in our clinical development programs may harm our business, financial condition, results of operations and prospects.

We will require substantial additional financing to achieve our goals and failure to obtain additional capital when needed, or on acceptable terms to us, could cause us to delay, limit, reduce, or terminate our product development or future commercialization efforts.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through equity offerings, debt financings, or other capital sources, including potential collaborations, licenses and other similar arrangements. 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 of these securities may include liquidation or other preferences that adversely affect your rights as a holder of our Class A Common Stock. Any future debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, selling or licensing our assets, making capital expenditures, declaring dividends or encumbering our assets to secure future indebtedness. Such restrictions could adversely impact our ability to conduct our operations and execute our business plan.

If we raise additional funds through future collaborations, licenses and other similar arrangements, we may have to relinquish valuable rights to our future revenue streams or product candidates, or grant licenses on terms that may not be favorable to us and/or that may reduce the value of our Class A Common Stock. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed or on terms acceptable to us, we would be required to delay, limit, reduce, or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Risks Related to Product Candidate Development and Commercialization

Our clinical trials may reveal significant adverse events not seen in our preclinical studies or prior clinical trials and may result in a safety or tolerability profile that could delay or prevent regulatory approval or market acceptance of izokibep, lonigutamab, any of our other product candidates or any future product candidates.

If significant adverse events or other side effects are observed in any of our clinical trials, we may have difficulty recruiting participants to our clinical trials, participants may drop out of our trials, or we may be required to abandon the trials or our development efforts of one or more product candidates altogether. Based on the safety profile of the two currently approved anti-IL-17A agents, ixekizumab and secukinumab, certain side effects are expected as part of inhibiting the IL-17A pathway. We have seen, and expect to see, similar results with izokibep, including AEs and potentially drug-related SAEs. These include injection site reactions, infections such as nasopharyngitis, and inflammatory bowel disease. In particular, the potential for new onset or exacerbation of inflammatory bowel disease is a known complication of IL-17 inhibition, is class labelling for all IL-17 inhibitors and therefore an exclusion criteria for our clinical trials of izokibep. Candida rates are expected to be observed in the 1-3% of trial participants. We expect that additional AEs and SAEs consistent with known side effects of IL-17A inhibitors may emerge in our ongoing and future clinical trials of izokibep.

If SAEs or other side effects are observed in any of our clinical trials that are atypical of, or more severe than, the known side effects of the respective class of agents that each of our product candidates are a part of, we may have difficulty recruiting participants to our clinical trials, participants may drop out of our trials, or we may be required to abandon those trials or our development efforts of one or more product candidates altogether. For example, two participants withdrew from our Phase 2 trial in PsA due to injection site reactions and erythema. While we believe that certain side effects could be reversible following discontinuation of izokibep or lonigutamab with sufficient recovery periods, we will need to monitor the severity and duration of side effects in our clinical trials. If such effects are more severe, less reversible than we expect or not reversible at all, we may decide or be required to perform additional studies or to halt or delay further clinical development of izokibep, lonigutamab which could result in the delay or denial of regulatory approval by the FDA or other regulatory authorities.

In addition, we believe that one of the benefits of lonigutamab is its potential to improve on the safety and side-effect profile of the sole currently approved therapy in the U.S. for the treatment of TED. If lonigutamab is shown to have similar AEs, side effects, or other safety or tolerability concerns, such as hearing impairment, then our opportunity to disrupt the current standard of care will be limited. AEs and SAEs that emerge during clinical investigation of or treatment with izokibep, lonigutamab, any of our other product candidates or any future product candidates may be deemed to be related to our product candidates. This may require longer and more

extensive clinical development, or regulatory authorities may increase the amount of data and information required to approve, market, or maintain izokibep, lonigutamab or any other current or future product candidates and could result in warnings and precautions in our product labeling or a restrictive risk evaluation and mitigation strategy (REMS). This may also result in an inability to obtain approval of izokibep, lonigutamab or any other current or future product candidates. We, the FDA, EMA or other applicable regulatory authorities, or an IRB, may suspend clinical trials of a product candidate at any time for various reasons, including a belief that participants in such trials are being exposed to unacceptable health risks or adverse side effects. Some potential product candidates developed in the biotechnology industry that initially showed promise in early-stage trials have later been found to cause side effects that prevented their further development. Even if the side effects do not preclude the product candidate from obtaining or maintaining marketing approval, undesirable side effects, like those mentioned above, may inhibit market acceptance of the approved product due to its tolerability versus other therapies. Any of these developments could materially harm our business, financial condition, results of operations and prospects.

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 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 participants enrollment continues and more participants data become available or as participants from our clinical trials continue other treatments for their disease. Adverse differences between 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 and could adversely affect 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, financial condition, results of operations and prospects. Further, disclosure of interim, top-line or preliminary data by us or by our competitors could result in volatility in the price of our Class A Common Stock after this offering.

Furthermore, if we fail to replicate the positive results from our preclinical studies or clinical trials in our future clinical trials, we may be unable to successfully develop, obtain regulatory approval for and commercialize our current or future product candidates.

We may expend our limited resources to pursue a particular product candidate in specific indications and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we focus our development efforts on certain selected product candidates in certain selected indications. For example, we are initially focused on our lead product candidates, izokibep for the treatment of HS, PsA, AxSpA and uveitis, and lonigutamab for the treatment of TED. As a result, we may forgo or delay pursuit of opportunities with other product candidates, or other indications for our existing product candidates that later prove to have greater commercial potential. 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 development programs and product candidates for specific indications may not yield any commercially viable product candidates. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, 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 to such product candidate.

We face competition from entities that have made substantial investments into the rapid development of novel treatments for immunological indications, including large and specialty pharmaceutical and biotechnology companies, many of which already have approved therapies in our current indications.

The development and commercialization of therapies is highly competitive. Our product candidates, if approved, will face significant competition, including from well-established, currently marketed therapies and our failure to demonstrate a meaningful improvement to the existing standard of care may prevent us from achieving significant market penetration. Many of our competitors have significantly greater resources and experience than we do and we may not be able to successfully compete. We face substantial competition from multiple sources, including large and specialty pharmaceutical and biotechnology companies, academic research institutions and governmental agencies and public and private research institutions. Our competitors compete with us on the level of the technologies employed, or on the level of development of their products as compared to our product candidates. In addition, many small biotechnology companies have formed collaborations with large, established companies to (i) obtain support for their research, development and commercialization of products or (ii) combine several treatment approaches to develop longer lasting or more efficacious treatments that may potentially directly compete with our current or any future product candidates. We anticipate that we will continue to face increasing competition as new therapies and combinations thereof, and related data emerge.

Our current product candidates, initially under development for treatment of various immunological indications, if approved, would face competition from existing approved immunological treatments, many of which have achieved commercial success. For example, we are currently developing izokibep for the treatment of HS, PsA, AxSpA and uveitis. Many emerging and established life sciences companies have been focused on similar therapeutics. If approved, izokibep would compete with currently approved therapeutics, including Cosentyx, Taltz, Humira, Remicade, Enbrel, Cimzia, Simponi, Stelara, Tremfya, Xeljanz, Otezla and Orencia for PsA; Humira for HS and uveitis; and Enbrel, Remicade, Humira, Cimzia, and Simponie for AxSpA. Izokibep would also compete with other drugs used to treat such patients, including generic drugs, such as biosimilar versions of Humira and Cosentyx, including Amjevita (marketed by Amgen Inc.), Abrilada (marketed by Pfizer Inc.), Avsola (marketed by Amgen Inc.), Cyltezo (marketed by Boehringer Ingelheim), Hadlima (marketed by Samsung Bioepis), Hulio (marketed by Boehringer Ingelheim), Hyrimoz (marketed by Sandoz), Ixifi (marketed by Pfizer Inc.), and Renflexis (marketed by Samsung Bioepis), among others we anticipate will receive approvals in the near term. There are also a number of product candidates in clinical development by third parties that are intended to treat HS, PsA, AxSpA and uveitis, including bimekizumab and sonelokimab.

We are also developing lonigutamab for the treatment of TED. The only approved product, Tepezza, has achieved wide-spread use in the treatment of TED. In addition to Tepezza, other therapies, such as corticosteroids, have been used on an off-label basis to alleviate some of the symptoms of TED. Immunovant Inc., Viridian Therapeutics, Inc. and Sling Therapeutics, Inc. are also conducting clinical trials of product candidates for the treatment of TED.

To compete successfully, we need to disrupt these currently marketed drugs, meaning that we will have to demonstrate that the relative cost, method of administration, safety, tolerability and efficacy of our product candidates provides a better alternative to existing and new therapies. Our commercial opportunity and likelihood of success will be reduced or eliminated if our product candidates are not ultimately demonstrated to be safer, more effective, more conveniently administered, or less expensive than the current standard of care. Furthermore, even if our product candidates are able to achieve these attributes, acceptance of our products may be inhibited by the reluctance of physicians to switch from existing therapies to our products, or if physicians choose to reserve our products for use in limited circumstances.

Many of our competitors have significantly greater financial, technical, manufacturing, marketing, sales and supply resources or experience than we have. If we obtain regulatory approval for any product candidate, we will face competition based on many different factors, including the safety and effectiveness of our current or any future product candidates, the ease with which our current or any future product candidates can be administered and the extent to which participants accept relatively new routes of administration, the timing and scope of regulatory approvals for these product candidates, the availability and cost of manufacturing, marketing and sales capabilities, price, reimbursement coverage and patent position. Competing products could present superior treatment alternatives, including by being more effective, safer, less expensive or marketed and sold more effectively than any products we may develop. Competitive products may make any products we develop obsolete or noncompetitive before we recover the expense of developing and commercializing our current or any future product candidates. Such competitors could also recruit our employees, which could negatively impact our level of expertise and our ability to execute our business plan.

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 management and other personnel and establishing clinical trial sites and participants registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

We are currently conducting, and may in the future conduct, clinical trials for current or future product candidates outside the U.S., and the FDA and comparable foreign regulatory authorities may not accept data from such trials.

We are currently conducting clinical trials outside the U.S., including in Europe and Australia, and we expect to continue to conduct trials internationally in the future. The acceptance of data from clinical trials conducted outside the U.S. or another jurisdiction by the FDA or comparable foreign regulatory authority may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the U.S., the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice and (ii) the trials were performed by clinical investigators of recognized competence and pursuant to GCP regulations. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. Many foreign regulatory authorities have similar approval requirements. In addition, such foreign trials are subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the U.S. or the applicable jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which could be costly and time-consuming, and which may result in current or future product candidates that we may develop being delayed or not receiving approval for commercialization in the applicable jurisdiction.

Even if we receive marketing approval for our current or future product candidates in the U.S., we may never receive regulatory approval to market outside of the U.S.

We plan to seek regulatory approval of our current or future product candidates outside of the U.S. and are currently conducting certain clinical trials internationally, including in Europe, the United Kingdom and Australia. In order to market any product outside of the U.S., however, we must establish and comply with the numerous and varying safety, efficacy and other regulatory requirements of other applicable countries. Approval procedures vary among countries and can involve additional product candidate testing and additional administrative review periods. The time required to obtain approvals in other countries might differ substantially from that required to obtain FDA approval. The marketing approval processes in other countries generally implicate all of the risks detailed above regarding FDA approval in the U.S. as well as other risks. In particular, in many countries outside of the U.S., products must receive pricing and reimbursement approval before the product can be commercialized. Obtaining this approval can result in substantial delays in bringing products to market in such countries. Marketing approval in one country does not ensure marketing approval in another, but a failure or delay in obtaining marketing approval in one country may have a negative effect on the regulatory process in others and would impair our ability to market our current or future product candidates in such foreign markets. Any such impairment would reduce the size of our potential market, which could adversely affect our business, financial condition, results of operations and prospects.

The successful commercialization of our product candidates, if approved, will depend in part on the extent to which governmental authorities and health insurers establish coverage, adequate reimbursement levels and favorable pricing policies. Failure to obtain or maintain coverage and adequate reimbursement for our product candidates could limit our ability to market those products and decrease our ability to generate revenue.

The availability of coverage and the adequacy of reimbursement by governmental healthcare programs such as Medicare and Medicaid, private health insurers and other third-party payors are essential for most patients to be able to afford prescription medications such as our product candidates, if approved. Our ability to achieve coverage and acceptable levels of reimbursement for our products by third-party payors will have an effect on our ability to successfully commercialize those products. Even if we obtain coverage for a given product by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. We cannot be sure that coverage and reimbursement in the United States, the European Union, Japan or elsewhere will be available for any product that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future.

Third-party payors increasingly are challenging prices charged for biopharmaceutical products and services, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs when equivalent generic drugs, biosimilars or less expensive therapies are available. It is possible that a third-party payor may consider our product candidates, if approved, as substitutable and only be willing to cover the cost of the alternative product. Even if we show improved efficacy, safety or improved convenience of administration with izokibep, lonigutamab or any of our product candidates, if approved, pricing of competitive products may limit the amount we will be able to charge for any of our product candidates, if approved. Third-party payors may deny or revoke the reimbursement status of a given product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in our product candidates. In some cases, when new competitor generic and biosimilar products enter the market, there are mandatory price reductions for the innovator compound. In other cases, payors employ “therapeutic category” price referencing and seek to lower the reimbursement levels for all treatments in the respective therapeutic category. Additionally, new competitor brand drugs can trigger therapeutic category reviews in the interest of modifying coverage and/or reimbursement levels. The potential of third-party payors to introduce more challenging price negotiation methodologies could have a negative impact on our ability to successfully commercialize any of our product candidates, if approved.

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products. In the United States, third-party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs will be covered. Some third-party payors may require pre-approval of coverage for new or innovative devices or therapies before they will reimburse healthcare providers who use such therapies. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our products, if approved.

Obtaining and maintaining reimbursement status is time consuming, costly and uncertain. The Medicare and Medicaid programs increasingly are used as models for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs. However, no uniform policy for coverage and reimbursement for products exists among third-party payors in the United States. 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 products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases at short notice, and we believe that changes in these rules and regulations are likely.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe and other countries has and will continue to put pressure on the pricing and usage of our products. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical products but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates, if approved. Accordingly, in markets outside the United States, the reimbursement for our product candidates may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our products. We expect to experience pricing pressures in connection with the sale of any of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products.

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 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 drug

designation for the indications we are evaluating, including moderate-to-severe HS, non-infectious uveitis and TED, or that we will be able to maintain such designation if granted.

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 to market the same drug for the same indication for seven years, except in limited circumstances. 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 izokibep in moderate-to-severe HS as well as non-infectious uveitis or lonigutamab in TED, 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 Our Business and Operations

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 product candidates, each of which is still in 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 and our ability to generate revenue, which we do not expect will occur for many years, if ever, are 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 preclinical and 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 COVID-19 or other pandemics. 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 FDA or comparable foreign regulatory authorities, and we may never receive sufficient regulatory approval that will allow us to successfully commercialize any 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 could adversely affect our business, financial condition, results of operations and prospects.

We have not previously submitted a BLA for our 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. The FDA may also consider its approvals of competing products, which may alter the treatment landscape concurrently with their review of our BLA submissions, 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 trial design. Such changes could delay approval or necessitate withdrawal of our BLA submissions.

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

- price our products competitively such that third-party and government reimbursement permits broad product adoption;
- demonstrate the superiority of our products compared to the standard of care, as well as other therapies in development;
- 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 populations and claims that are necessary or desirable for successful marketing;
- effectively commercialize any of our products that receive regulatory approval;
- manufacture product candidates through contract manufacturing organizations (CMOs) 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 products;
- 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 products by patients, the medical community, and third-party payors;
- 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; and
- assure that our product will be used as directed and that additional unexpected safety risks will not arise.

Our planned Phase 3 clinical trials of izokibep for moderate-to-severe HS as well as non-infectious uveitis, even if successfully completed, may not be sufficient for approval of izokibep for the applicable indication.

We are evaluating izokibep in both moderate-to-severe HS as well as non-infectious uveitis as orphan indications, potentially eligible for orphan drug designation by regulatory authorities. In each case, assuming this orphan designation is granted, and subject to discussions with the relevant heath authorities, we are conducting the ongoing Phase 2b/3 trials in these indications to potentially enable inclusion of data from such trials in our future registrational package, enabling us to conduct only one additional confirmatory Phase 3 clinical trial for each indication. FDA approval of a new biologic or drug generally requires dispositive data from two well-controlled, Phase 3 clinical trials of the relevant biologic or drug in the relevant patient population. Although we have discussed our plans with the FDA, we do not have any formal agreement or guidance from the FDA that our

regulatory development plans will be sufficient for submission of a BLA. The FDA may require that we conduct an additional comparative trial against an approved therapy, which would significantly delay our development timelines and require substantially more resources. In addition, the FDA may only allow us to evaluate a subset of participants that have failed or who are ineligible for approved therapies, which are extremely difficult participants to treat and participants with advanced and aggressive disease, and our product candidates may fail to improve outcomes for such participants. Generally speaking, Phase 3 clinical trials typically involve hundreds of patients, have significant costs and take years to complete. If we are required to conduct two Phase 3 clinical trials for each of moderate-to-severe HS as well as non-infectious uveitis, then our development timeline would be extended, and the related expenses would be significantly increased.

In addition, if the FDA grants approval for our product candidates then, as a condition for approval, the FDA may require us to perform post-marketing studies to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical endpoint, and izokibep may be subject to withdrawal procedures by the FDA. If the FDA does not agree with our planned strategy, the FDA may ultimately require more Phase 3 clinical trials prior to approval in either indication. In addition, the standard of care may change with the approval of new products in the same indications that we are studying. This may result in the FDA or other regulatory agencies requesting additional studies to show that our product candidate is superior to the new products.

Our clinical trial results may also not support approval. In addition, our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that our product candidates are safe and effective for any of their proposed indications;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval, including due to the heterogeneity of patient populations, or apparent improvement in trial participants receiving placebo;
- we may be unable to demonstrate that our product candidates' clinical and other benefits outweigh their safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to the satisfaction of the FDA or comparable foreign regulatory authorities to support the submission of a BLA or other comparable submission in foreign jurisdictions or to obtain regulatory approval in the U.S. or elsewhere;
- the FDA or comparable foreign regulatory authorities will review CMOs' manufacturing process and inspect our CMOs' commercial manufacturing facilities and may not approve our CMOs' manufacturing process or facilities; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

If our product candidates, if approved, do not achieve broad market acceptance, the revenue 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 revenue or become profitable.

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, efficacy, tolerability and ease of administration of our product candidates;
- the prevalence and severity of side effects and adverse events associated with our product candidates, and how the safety and tolerability profile of our product candidates compares to those of existing therapies, or those under development;
- 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 REMS 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' current standard of care;
- the reluctance of patients to switch from their existing therapy regardless of the safety and efficacy of newer products;
- 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 revenue from our product candidates and may never become profitable.

We will need to grow our organization, and we may experience difficulties in managing our growth and expanding our operations, which could adversely affect our business.

As of December 31, 2022, we had 47 full-time employees. As our development and commercialization plans and strategies develop, and as we transition into operating as a public company, we expect to expand our

employee base for managerial, operational, financial and other resources. In addition, we have limited experience in manufacturing and commercialization. As our product candidates enter and advance through preclinical studies and clinical trials, we will need to expand our development and regulatory capabilities and contract with other organizations to provide manufacturing and other capabilities for us. In the future, we expect to have to manage additional relationships with collaborators or partners, suppliers and other organizations. Our ability to manage our operations and future growth will require us to continue to improve our operational, financial and management controls, reporting systems and procedures. We may not be able to implement improvements to our management information and control systems in an efficient or timely manner and may discover deficiencies in existing systems and controls. Our inability to successfully manage our growth and expand our operations could adversely affect our business, financial condition, results of operations and prospects.

We are dependent on the services of our management and other clinical and scientific personnel, and if we are not able to retain these individuals or recruit additional management or clinical and scientific personnel, our business will suffer.

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel. We are highly dependent upon our Founder and Chief Executive Officer, Shao-Lee Lin, M.D., Ph.D., and other members of our management team. The loss of services of any of these individuals could delay or prevent the successful development of our product pipeline, initiation or completion of our preclinical studies and clinical trials or the commercialization of our product candidates. Although we have executed employment agreements or offer letters with each member of our senior management team, these agreements are terminable at will with or without notice and, therefore, we may not be able to retain their services as expected. We do not currently maintain “key person” life insurance on the lives of our executives or any of our employees. This lack of insurance means that we may not have adequate compensation for the loss of the services of these individuals.

We will need to expand and effectively manage our managerial, operational, financial and other resources in order to successfully pursue our clinical development and commercialization efforts. We may not be successful in maintaining our unique company culture and continuing to attract or retain qualified management and scientific and clinical personnel in the future due to the intense competition for qualified personnel among biopharmaceutical, biotechnology and other businesses, particularly in the Los Angeles area and the greater San Francisco Bay Area. If we are not able to attract, integrate, retain and motivate necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy.

Our employees, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk of employee fraud or other illegal activity by our employees, independent contractors, consultants, commercial partners, CROs, CMOs and vendors. Misconduct by these parties could include intentional, reckless and/or negligent conduct that fails to comply with FDA or other regulations, provide true, complete and accurate information to the FDA, EMA and other similar foreign regulatory bodies, comply with manufacturing standards we may establish, comply with healthcare fraud and abuse laws and regulations, report financial information or data accurately or 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 these laws will increase significantly, and our costs associated with compliance with these laws are likely to increase. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended 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, sales commission, customer incentive programs and other business arrangements.

Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity 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. 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 material and adverse effect on our business, financial condition, results of operations and prospects, including the imposition of significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, the curtailment or restructuring of our operations, loss of eligibility to obtain approvals from the FDA, exclusion from participation in government contracting, healthcare reimbursement or other government programs, including Medicare and Medicaid, integrity oversight and reporting obligations, or reputational harm.

Our future growth may depend, in part, on our ability to operate in foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.

Our future growth may depend, in part, on our ability to develop and commercialize our product candidates in foreign markets, including in the European Union (EU), United Kingdom (UK) and Japan, for which we may rely on collaboration with third parties. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the applicable regulatory authority in that foreign market, and may never receive such regulatory approval for any of our product candidates. To obtain separate regulatory approval in many other countries, we must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy and governing, among other things, clinical trials and commercial sales, pricing and distribution of our product candidates, and we cannot predict success in these jurisdictions. If we fail to comply with the regulatory requirements in international markets and 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 and our business will be adversely affected. We may not obtain foreign regulatory approvals on a timely basis, if at all. Our failure to obtain approval of any of our product candidates by regulatory authorities in another country may significantly diminish the commercial prospects of that product candidate and our business, financial condition, results of operations and prospects could be adversely affected. Moreover, even if we obtain approval of our product candidates and ultimately commercialize our product candidates in foreign markets, we would be subject to the risks and uncertainties, including the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements and reduced protection of intellectual property rights in some foreign countries.

Our business entails a significant risk of product liability and our ability to obtain sufficient insurance coverage could adversely affect our business, financial condition, results of operations and prospects.

As we conduct clinical trials of our current or future product candidates, we are exposed to significant product liability risks inherent in the development, testing, manufacturing and marketing of new treatments. Product liability claims could delay or prevent completion of our development programs. If we succeed in marketing products, such claims could result in FDA, EMA or other investigation of the safety and effectiveness of our future product candidates, our manufacturing processes and facilities or our marketing programs and potentially a recall of our products or more serious enforcement action, limitations on the approved indications for which they may be used or suspension or withdrawal of approvals. Regardless of the merits or eventual outcome, liability claims may also result in decreased demand for our product candidates, termination of clinical trial sites or entire trial programs, withdrawal of clinical trial participants, injury to our reputation and significant negative media attention, significant costs to defend the related litigation, a diversion of management's time and our resources from our business operations, substantial monetary awards to trial participants or patients, loss of revenue, the inability to commercialize and products that we may develop, and a decline in our stock price. We

may need to obtain higher levels of product liability insurance for later stages of clinical development or marketing any of our product candidates. Any insurance we may obtain may not provide sufficient coverage against potential liabilities. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to obtain sufficient insurance at a reasonable cost to protect us against losses caused by product liability claims that could adversely affect our business, financial condition, results of operations and prospects.

Our insurance policies are expensive and only protect us from some business risks, which will leave us exposed to significant uninsured liabilities.

We do not carry insurance for all categories of risk that our business may encounter. Some of the policies we currently maintain include workers' compensation, clinical trials, and directors' and officers' liability insurance. We do not know, however, if we will be able to maintain insurance with adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our business, financial condition, results of operations and prospects.

We recently acquired ValenzaBio, and we expect to engage in strategic transactions in the future, which could impact our liquidity, increase our expenses and present significant distractions to our management.

As a core part of our strategy, we intend to enter into strategic transactions, including acquisitions of companies, asset purchases and in-licensing of intellectual property with the potential to acquire and advance new assets or product candidates where we believe we are well qualified to optimize the development of promising therapies. For example, we recently completed the acquisition of ValenzaBio, Inc. through which we have acquired certain development and marketing rights, including to lonigutamab and XLRN-517. Our ability to realize the anticipated benefits of the acquisition of ValenzaBio depends, to a large extent, on our ability to continue the development of lonigutamab and XLRN-517, in which we have limited experience. The expected synergies in development programs, pipelines and other areas of focus between our company and ValenzaBio may not be realized on a timely basis or at all, and there may be risks associated with the acquisition that we did not previously anticipate. For example, we may learn of unanticipated liabilities that we have now assumed.

Additional potential transactions that we may consider in the future include a variety of business arrangements, including strategic partnerships, in-licensing of product candidates, strategic collaborations, joint ventures, restructurings, divestitures, business combinations and investments. Any future transactions could increase our near and long-term expenditures, result in potentially dilutive issuances of our equity securities, including our Class A Common Stock, or the incurrence of debt, contingent liabilities, amortization expenses or acquired in-process research and development expenses, any of which could affect our financial condition, liquidity and results of operations.

Future acquisitions may also require us to obtain additional financing, which may not be available on favorable terms or at all. These transactions may never be successful and may require significant time and attention of our management. In addition, the integration of any business that we may acquire in the future may disrupt our existing business and may be a complex, risky and costly endeavor for which we may never realize the full benefits of the acquisition. Accordingly, although there can be no assurance that we will undertake or successfully complete any additional transactions of the nature described above, any additional transactions that we do complete could adversely affect our business, financial condition, results of operations and prospects.

Our ability to use our net operating loss (NOL) carryforwards and certain other tax attributes to offset taxable income or taxes may be limited.

We have incurred substantial losses during our history and do not expect to become profitable in the near future, and we may never achieve profitability. As of December 31, 2022, we had federal NOL carryforwards of $ million and state NOL carryforwards of $ million. Under the Internal Revenue Code of

1986, as amended (the Code), our U.S. federal net operating losses will not expire and may be carried forward indefinitely but the deductibility of federal net operating losses is limited to no more than 80% of current year taxable income (with certain adjustments). In addition, under Sections 382 and 383 of the Code, if a corporation undergoes an "ownership change," generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three-year period, the corporation's ability to use its pre-change NOL carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. We have not completed a Section 382 study to assess whether an ownership change has occurred or whether there have been multiple ownership changes since our formation due to the complexity and cost associated with such a study and the fact that there may be additional ownership changes in the future some of which may be outside of our control. As a result, if we undergo an ownership change, and our ability to use our pre-change NOL carryforwards and other pre-change tax attributes (such as research tax credits) to offset our post-change income or taxes is limited, it would harm our future results of operations by effectively increasing our future tax obligations. Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes. In addition, at the state level, there may be periods during which the use of net operating losses is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. As a result, even if we attain profitability, we may be unable to use all or a material portion of our net operating losses and other tax attributes, which could adversely affect our future cash flows.

Recent and future changes to tax laws could materially adversely affect our company.

The tax regimes we are subject to or operate under, including with respect to income and non-income taxes, are unsettled and may be subject to significant change. Changes in tax laws, regulations, or rulings, or changes in interpretations of existing laws and regulations, could materially adversely affect our company. For example, the Tax Cuts and Jobs Act, the Coronavirus Aid, Relief, and Economic Security Act, and the Inflation Reduction Act (the IRA) enacted many significant changes to the U.S. tax laws. Future guidance from the Internal Revenue Service and other tax authorities with respect to such legislation may affect us, and certain aspects thereof could be repealed or modified in future legislation. For example, the IRA includes provisions that will impact the U.S. federal income taxation of certain corporations, including imposing a 15% minimum tax on the book income of certain large corporations and a 1% excise tax on certain corporate stock repurchases that would be imposed on the corporation repurchasing such stock. In addition, many countries in Europe, as well as a number of other countries and organizations (including the Organization for Economic Cooperation and Development and the European Commission), have proposed, recommended, or (in the case of countries) enacted or otherwise become subject to changes to existing tax laws or new tax laws that could significantly increase our tax obligations in the countries where we do business or require us to change the manner in which we operate our business.

If our internal information technology systems, or those used by our CROs, CMOs, clinical sites or other contractors or consultants upon which we rely, are or were compromised, become unavailable or suffer security breaches, loss or leakage of data or other disruptions, we could suffer material adverse consequences resulting from such compromise, including but not limited to, operational or service interruption, harm to our reputation, litigation, fines, penalties and liability, compromise of sensitive information related our business, and other adverse consequences.

In the ordinary course of our business, we, and the third parties upon which we rely, process sensitive data and as a result, we and the third parties upon which we rely face a variety of evolving threats which could cause security incidents.

Our internal information technology systems and those of our CROs, CMOs, clinical sites and other contractors and consultants upon which we rely are vulnerable to cyberattacks, computer viruses, bugs, worms, or other malicious codes, malware (including as a result of advanced persistent threat intrusions), and other attacks by computer hackers, cracking, application security attacks, social engineering (including through phishing attacks), supply chain attacks and vulnerabilities through our third-party service providers, denial-of-service attacks (such as credential stuffing), credential harvesting, personnel misconduct or error,

supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, earthquakes, fires, floods, and other similar threats.

Such threats are prevalent and continue to rise, are increasingly difficult to detect, and come from a variety of sources, including traditional computer "hackers," threat actors, "hacktivists," organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation-state-supported actors. In particular, 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 negative 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).

Some actors also now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors, for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we, the third parties upon which we rely, and our customers may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our goods and services. In addition to experiencing a security incident, third parties may gather, collect, or infer sensitive information about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position.

Additionally, remote work has become more common and has increased risks to our information technology systems and data, as more of our employees utilize network connections, computers and devices outside our premises or network, including working at home, while in transit and in public locations.

Furthermore, future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Additionally, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

While we take steps to detect and remediate vulnerabilities, we may not be able to detect and remediate all vulnerabilities because the threats and techniques used to exploit such vulnerabilities change frequently and are often sophisticated in nature. Therefore, such vulnerabilities could be exploited but may not be detected until after a security incident has occurred. Further, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities.

We rely on third-party service providers and technologies to operate critical business systems to process sensitive information in a variety of contexts, including, without limitation, cloud-based infrastructure, encryption and authentication technology, employee email, and other functions. We also rely on third-party service providers to assist with our clinical trials, provide other products or services, or otherwise to operate our business. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If our third-party service providers experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if our third-party service providers fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties and infrastructure in our supply chain or our third-party partners' supply chains have not been compromised or that they do not contain exploitable defects or bugs that could result in a breach of or disruption to our information technology systems (including our services) or the third-party information technology systems that support us and our services.

Any of the previously identified or similar threats could cause a security incident or other interruption that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive data or our information technology systems, or those of the third parties upon whom we rely. A security incident or other interruption could disrupt our ability (and that of third parties upon whom we rely) to provide our services including clinical trials.

The costs related to significant security breaches or disruptions could be material and cause us to incur significant expenses. If the information technology systems of our CROs, CMOs, clinical sites and other contractors and consultants become subject to disruptions or security incidents, we may have insufficient recourse against such third parties and we may have to expend significant resources to mitigate the impact of such an event, and to develop and implement protections to prevent future events of this nature from occurring.

If any such incidents were to occur and cause interruptions in our operations, it could result in a disruption of our business and 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 in the future. To the extent that any disruption or security incident were to result in the 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. Applicable data privacy and security obligations may require us to notify relevant stakeholders of security incidents. Such disclosures are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences. 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.

Our operations are concentrated in one location, and we or the third parties upon whom we depend may be adversely affected by a wildfire and earthquake or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Our current operations are predominantly located in California. Any unplanned event, such as flood, wildfire, explosion, earthquake, extreme weather condition, medical epidemic including the COVID-19 pandemic, power shortage, telecommunication failure or other natural or manmade accidents or incidents that result in us being unable to fully utilize our facilities may have a material and adverse effect on our ability to operate our business, particularly on a daily basis, and have significant negative consequences on our financial and operating conditions. Any similar impacts of natural or manmade disasters on our third-party CMOs and CROs located globally, could cause delays in our clinical trials and may have a material and adverse effect on our ability to operate our business and have significant negative consequences on our financial and operating conditions. If a natural disaster, power outage or other event occurred that prevented us from using our clinical sites, impacted clinical supply or the conduct of our clinical trials, that damaged critical infrastructure, such as the manufacturing facilities of our third-party CMOs, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we and our CMOs and CROs have in place may prove inadequate in the event of a serious disaster or similar event. As part of our risk management policy, we maintain insurance coverage at levels that we believe are appropriate for our business. However, in the event of an accident or incident at these facilities, we cannot assure you that the amounts of insurance will be sufficient to satisfy any damages and losses. If our facilities, or the manufacturing facilities of our CMOs, are unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of our development programs may be harmed. Any business interruption could adversely affect our business, financial condition, results of operations and prospects.

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.

The precise incidence and prevalence for all the conditions we aim to address with our product candidates are unknown. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases 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 sales of our competitors, scientific literature, surveys of clinics, patient foundations or market research, and may prove to be incorrect in general, or as to their applicability to our company. Further, new trials may change the estimated incidence or prevalence of these diseases. The total addressable market across all of our product candidates will ultimately depend upon, among other things, the diagnosis criteria included in the final label for each of our product candidates approved for sale for these indications, the ability of our product candidates to improve on the safety, convenience, cost and efficacy of competing therapies or therapies in development, acceptance by the medical community and patients, drug pricing and reimbursement. The number of patients in the United States and other major markets and elsewhere may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our product candidates or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our business, financial condition, results of operations and prospects. Further, even if we obtain significant market share for our product candidates, because some of our potential target populations are very small, we may never achieve profitability despite obtaining such significant market share.

Our business could be adversely affected by the effects of health pandemics or epidemics, including the ongoing COVID-19 pandemic, which could cause significant disruptions in our operations and those of our CMOs, CROs and other third parties upon whom we rely.

Health pandemics or epidemics, including the ongoing COVID-19 pandemic, have in the past and could again in the future result in quarantines, stay-at-home orders, remote work policies or other similar events that may disrupt businesses, delay our research and development programs and timelines, negatively impact productivity and increase risks associated with cybersecurity, the future magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations. More specifically, these types of events may negatively impact personnel at third-party manufacturing facilities or the availability or cost of materials, which could disrupt our supply chain. Moreover, our trials may be negatively affected. Clinical site initiation and patient enrollment may be delayed due to prioritization of hospital resources. Some patients may not be able or willing to comply with trial protocols if quarantines impede patient movement or interrupt healthcare services. Our ability to recruit and retain patients, principal investigators and site staff (who as healthcare providers may have heightened exposure) may be hindered, which would adversely affect our trial operations. Disruptions or restrictions on our ability to travel to monitor data from our trials, or to conduct trials, or the ability of patients enrolled in our trials or staff at trial sites to travel, as well as temporary closures of our trial partners and CMOs' facilities, would negatively impact our trial activities. In addition, we rely on independent clinical investigators, CROs and other third-party service providers to assist us in managing, monitoring and otherwise carrying out our preclinical studies and clinical trials, including the collection of data from our trials, and the effects of health pandemics or epidemics, including the ongoing COVID-19 pandemic, may affect their ability to devote sufficient time and resources to our programs or to travel to sites to perform work for us. Similarly, our trials could be delayed and/or disrupted. As a result, the expected timeline for data readouts, including incompleteness in data collection and analysis and other related activities, and certain regulatory filings may be negatively impacted, which would adversely affect our ability to obtain regulatory approval for and to commercialize our product candidates, increase our operating expenses and adversely affect our business, financial condition, results of operations and prospects. In addition, impact on the operations of the FDA or other regulatory authorities could negatively affect our planned trials and approval processes. Finally, economic conditions and business activity may be negatively impacted and may not recover as quickly as anticipated. To date, the COVID-19 pandemic has had a limited impact on our research and development activities related to izokibep, lonigutamab and our other product candidates, other than, in certain cases, prices and access to raw materials; however, the effects of the COVID-19 pandemic continue to evolve and as a result, the ultimate impact of the COVID-19 pandemic (or a similar health pandemic or epidemic) is highly uncertain and subject to change.

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 immunology treatments in general could result in greater government regulation and stricter labeling requirements of products to treat immunological diseases, including any of our product candidates, if approved, and could cause a decrease in the demand for any product candidates we may develop. For example, approximately 10% of participants in Phase 2 and Phase 3 trials for teprotumumab reported developing hearing impairment symptoms and a further study conducted by Stanford University in 28 participants receiving teprotumumab suggested that the rate could be over 45%. If the public or medical professionals associate these side effects with all IGF-1R therapies, market acceptance of our product candidates, if approved, may be negatively impacted. Similarly, side effects generally associated with IL-17A inhibitors may negatively impact public perception of us or izokibep. Adverse public attitudes may also 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 withdrawal of clinical trial participants, 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 have identified material weaknesses in our internal control over financial reporting. If we fail to remediate these material weaknesses, or if we experience additional material weaknesses in the future or otherwise fail to maintain effective internal control over financial reporting in the future, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our Class A Common Stock.

As of December 31, 2021, we had limited accounting personnel and other resources to address our internal control over financial reporting. In connection with the preparation of our financial statements for the year ended December 31, 2021, material weaknesses were identified in the design and operating effectiveness of our internal control over financial reporting. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis.

These material weaknesses are related to the fact that we lacked a sufficient number of professionals to consistently establish appropriate authorities and responsibilities in pursuit of our financial reporting objectives. The lack of sufficient number of finance and accounting professionals further contributed to the following additional material weaknesses. We did not design and maintain an effective risk assessment process at a precise enough level to identify new and evolving risks of material misstatement in the financial statements. Additionally, we did not design and maintain effective controls over the segregation of duties related to journal entries and account reconciliations. Specifically, certain personnel had the ability to both (i) create and post journal entries within the company's general ledger system and (ii) prepare and review account reconciliations without a review performed by someone without conflicting duties.

There were no adjustments that resulted from the above material weaknesses. However, these material weaknesses could result in a misstatement of substantially all of our accounts or disclosures that would result in a material misstatement of our annual or interim financial statements that would not be prevented or detected.

To remediate the material weaknesses, we have begun to hire additional accounting personnel, as well as have engaged a third-party firm to assist in the design and implementation of controls. We are in the process of implementing formal risk assessment processes and procedures and designing sufficient controls to remediate these weaknesses. We intend to continue to take steps to remediate these material weaknesses through the hiring of additional experienced accounting and financial reporting personnel, formalizing documentation of policies and procedures and further evolving the accounting processes, including implementing appropriate segregation of duties. The material weaknesses will not be considered remediated until management completes the design and implementation of the measures described above and the controls operate for a sufficient period of time and management has concluded, through testing, that these controls are effective.

The measures we have taken to date, and are continuing to design and implement, may not be sufficient to remediate the material weaknesses we have identified or avoid potential future material weaknesses. If the steps we take do not correct these material weaknesses in a timely manner, we will be unable to conclude that we maintain effective internal control over financial reporting. Accordingly, there could continue to be a reasonable possibility that a material misstatement of our financial statements would not be prevented or detected on a timely basis.

If we fail to remediate our existing material weaknesses or identify new material weaknesses in our internal control over financial reporting, if we are unable to comply with the disclosure and attestation requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, if we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm is unable to conclude that our internal control over financial reporting is effective when 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 Class A Common Stock could be negatively affected. As a result, we could also become subject to investigations by the Nasdaq Global Market, the SEC or other regulatory authorities, and become subject to litigation from investors and stockholders, which could harm our reputation and financial condition or divert financial and management resources from our regular business activities.

Risks Related to Intellectual Property

If we are unable to obtain and maintain sufficient intellectual property protection for our product candidates and any future product candidates we may develop, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors or other third parties could develop and commercialize products similar or identical to ours, and our ability to successfully develop and commercialize our product candidates may be adversely affected.

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

Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries for our product candidates and their uses, as well as our ability to operate without infringing, misappropriating or otherwise violating the proprietary rights of others. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our novel discoveries and technologies that are important to our business. Although we in-license issued patents, we do not own any issued patents and our pending and future patent applications may not result in patents being issued. We cannot assure you that issued patents will 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 technologies, products or product candidates.

Obtaining and enforcing patents is expensive and time-consuming, and we may not be able to file, prosecute, maintain, enforce or license 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 or our licensors' operations. We may not be able to obtain or maintain patent applications and patents due to the subject matter claimed in such patent applications and patents being in disclosures in the public domain. 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 confidential or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, CROs, CMOs, 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. Consequently, we may not be able to prevent any third parties from using any of our technology that is in the public domain to compete with our technologies or product candidates.

Composition of matter patents for biological and 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. However, we cannot be certain that the claims in our or our collaborators' or licensors' 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 or our licensors' 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 candidates for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their product for our targeted indications, clinicians 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. As a result, the issuance, scope, validity, enforceability and commercial value of any patent rights are highly uncertain. Our pending and future owned and in-licensed patent applications may not result in patents being issued which protect our technologies or product candidates, effectively prevent others from commercializing our technologies or product candidates or otherwise provide any competitive advantage. In fact, patent applications may not issue as patents at all. The coverage claimed in a patent application can also be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. 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 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 or our licensors' patents and patent applications, as well as the impact of such third-party intellectual property upon our freedom to operate, is highly uncertain. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and 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. If a third party can establish that we or our licensors were not the first to make or the first to file for patent protection of such inventions, our owned or licensed patent applications may not issue as patents and even if issued, may be challenged and invalidated or rendered unenforceable. As a result, the issuance, inventorship, scope, validity, enforceability and commercial value of our or our licensors' patent rights are highly uncertain.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability and our or our licensors' 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 or our licensors' 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, interferences, inter partes review (IPR) proceedings or other similar proceedings, in the United States or elsewhere, challenging our or our licensors' patent rights or the patent rights of others. Such submissions may also be made prior to a patent's issuance, precluding the granting of a patent based on one or more of our owned or licensed pending patent applications. 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 technology and product candidates, or limit the duration of the patent protection of our technology and product candidates. Such challenges also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. Any of the foregoing could adversely affect our business, financial condition, results of operations and prospects.

A third party may also claim that our owned or licensed patent rights are invalid or unenforceable in a litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. An adverse result in any legal proceeding could put one or more of our owned or in-licensed patents at risk of being invalidated or interpreted narrowly and could allow third parties to commercialize our products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize our technology, products or product candidates without infringing third-party patent rights.

In addition, 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 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 adversely affect our business, financial condition, results of operations and prospects.

We have in-licensed issued patents, but we do not currently own any issued patents relating to our technology, products and product candidates.

Although we exclusively in-license issued patents from Affibody AB (Affibody) and Pierre Fabre Medicament SAS (Pierre Fabre) related to izokibep and lonigutamab, respectively, we do not own or license any other issued patents. Additionally, we exclusively in-license one pending non-provisional patent application and two pending Patent Cooperation Treaty (PCT) applications for XLRN-517, but do not own or exclusively in-license any issued patents relating to such product candidate and there can be no assurance that we will obtain any issued patents directed to XLRN-517. We cannot be certain that the claims in our U.S. pending patent applications, corresponding international patent applications and patent applications in certain foreign jurisdictions, or those of our licensors, will be considered patentable by the USPTO, courts in the United States or by the patent offices and courts in foreign countries, nor can we be certain that any issued claims will not be found invalid or unenforceable if challenged. Additionally, our provisional applications may never result in issued patents. Accordingly, there can be no assurance that we or our licensors will obtain any additional issued patents or that any issued patents we or our licensors obtain will provide us with any competitive advantage. Any failure to obtain adequate patent protection for our product candidates and technology could adversely affect our business, financial condition, results of operations and prospects.

Our rights to develop and commercialize our product candidates are subject, in large part, to the terms and conditions of licenses granted to us by others, such as Affibody and Pierre Fabre. If we fail to comply with our obligations in the agreements under which we in-license or acquire development or commercialization rights to product candidates, or data from third parties, we could lose such rights that are important to our business.

We are heavily reliant upon licenses to certain patent rights and other intellectual property that are important or necessary to the development of izokibep and lonigutamab or our other current or future product candidates. For example, we depend on licenses from Affibody and Pierre Fabre for certain intellectual property relating to the development and commercialization of izokibep and lonigutamab, respectively. However, we have no development, commercialization, and manufacturing rights for izokibep in Mainland China, Hong Kong, Macau, South Korea and Taiwan as well as development rights in certain other Asia-Pacific countries, all of which rights have been granted by Affibody to Inmagene Biopharmaceuticals (Inmagene), under a pre-existing license agreement (the Inmagene Agreement).

Affibody and Pierre Fabre may have relied upon, and any future licensors may rely upon, third-party companies, consultants or collaborators, or on funds from third parties such that our licensors are not the sole and exclusive owners of the patents we in-licensed. If our licensors, including Affibody and Pierre Fabre, fail to prosecute, maintain, enforce, and defend such patents, or lose rights to those patents, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize izokibep, lonigutamab or our other current or future product candidates that are or may be the subject of such licensed rights could be adversely affected. Further development and commercialization of izokibep, lonigutamab, and development of any future product candidates may, require us to enter into additional license or collaboration agreements. For example, our licensors or other third parties may develop intellectual property covering izokibep and lonigutamab which we have not licensed. Our future licenses may not provide us with exclusive rights to use the licensed patent rights and other intellectual property licensed thereunder, or may not provide us with exclusive rights to use such patent rights and intellectual property in all relevant fields of use and in all territories in which we wish to develop or commercialize izokibep, lonigutamab or our other product candidates in the future.

In spite of our efforts, Affibody, Pierre Fabre or any future licensors might conclude that we are in material breach of obligations under our license agreements and may therefore have the right to terminate the license agreements, thereby removing our ability to develop and commercialize product candidates and technology covered by such license agreements. If such in-licenses are terminated, or if the underlying patents fail to provide the intended exclusivity, our competitors would have the freedom to seek regulatory approval of, and to market, products identical to our product candidates and the licensors to such in-licenses could prevent us from developing or commercializing product candidates that rely upon the patents or other intellectual property rights which were the subject matter of such terminated agreements. In addition, we may seek to obtain additional licenses from our licensors and, in connection with obtaining such licenses, we may agree to amend our existing licenses in a manner that may be more favorable to the licensors, including by agreeing to terms that could enable third parties (potentially including our competitors) to receive licenses to a portion of the intellectual property that is subject to our existing licenses and compete with our existing product candidates. Any of these events could adversely affect our business, financial condition, results of operations, and prospects.

Disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- our financial or other obligations under the license agreement;
- the extent to which our processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those obligations;

- the inventorship or ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

In addition, our license agreements are, and future license agreements are likely to be, complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could adversely affect our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could adversely affect our business, financial condition, results of operations, and prospects.

We may not be successful in obtaining or maintaining necessary rights to our product candidates through acquisitions and in-licenses.

Because our development programs may in the future require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license, or use these third-party proprietary rights. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary for our product candidates on commercially reasonable terms or at all. Even if we are able to in-license any such necessary intellectual property, it could be on nonexclusive terms, thereby giving our competitors and other third parties access to the same intellectual property licensed to us, and it could require us to make substantial licensing and royalty payments. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of 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. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have obtained, we may have to abandon development of the relevant program or product candidate, which could adversely affect our business, financial condition, results of operations, and prospects.

While we normally seek to obtain the right to control prosecution, maintenance and enforcement of the patents relating to our product candidates, there may be times when the filing and prosecution activities for patents and patent applications relating to our product candidates are controlled by our future licensors or collaboration partners. If any of our future licensors or collaboration partners fail to prosecute, maintain and enforce such patents and patent applications in a manner consistent with the best interests of our business, including by payment of all applicable fees for patents covering our product candidates, we could lose our rights to the intellectual property or our exclusivity with respect to those rights, our ability to develop and commercialize those product candidates may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products. In addition, even where we have the right to control patent prosecution of patents and patent applications we have licensed to and from third parties, we may still be adversely affected or prejudiced by actions or inactions of our licensees, our future licensors and their counsel that took place prior to the date upon which we assumed control over patent prosecution.

We may enter into license agreements in the future with others to advance our existing or future research or allow commercialization of our existing or future product candidates. These licenses may not provide exclusive rights to use such intellectual property and technology in all relevant fields of use and in all territories in which

we may wish to develop or commercialize our technology and product candidates in the future. In that event, we may be required to expend significant time and resources to redesign our product candidates, or the methods for manufacturing them, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could harm our business, financial condition, results of operations, and prospects significantly. We cannot provide any assurances that third-party patents do not exist which might be enforced against our current manufacturing methods, product candidates, or future methods or product candidates resulting 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 form or seek collaborations or strategic alliances or enter into additional licensing arrangements in the future, and we may not realize the benefits of such alliances or licensing arrangements.

Any future collaborations that we enter into may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborations are subject to numerous risks, which may include that:

- collaborators have significant discretion in determining the efforts and resources that they will apply to collaborations;
- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on trial or test results, changes in their strategic focus due to the acquisition of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities, or the ongoing COVID-19 pandemic;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates;
- a collaborator with marketing, manufacturing and distribution rights to one or more products may not commit sufficient resources to or otherwise not perform satisfactorily in carrying out these activities;
- we could grant exclusive rights to our collaborators that would prevent us from collaborating with others;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that causes the delay or termination of the research, development or commercialization of our future product candidates or that results in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated, and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable future product candidates;
- collaborators may own or co-own intellectual property covering our product candidates that results from our collaborating with them, and in such cases, we would not have the exclusive right to develop or commercialize such intellectual property; and
- a collaborator’s sales and marketing activities or other operations may not be in compliance with applicable laws resulting in civil or criminal proceedings.

We cannot ensure that patent rights relating to inventions described and claimed in our or our licensors' pending patent applications will issue or that patents based on our or our licensors' 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, our licensors, or any of our potential future collaborators will be successful in protecting our product candidates by obtaining and defending patents. We have several pending U.S. and foreign patent applications in our portfolio. 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
- whether, if 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 or our licensors' pending patent applications directed to our product candidates and/or technologies 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 and our licensors' 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 or our licensors' patent claims or, if issued, affect the validity or enforceability of a patent claim. Even if the patents do issue based on our or our licensors' 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 and our licensors' 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. Filing, prosecuting and defending patents on all of our research programs and product candidates in all countries throughout the world would be prohibitively expensive, and our and our licensors' 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, even in jurisdictions where we do pursue patent protection. Consequently, we may not be able to prevent third parties from practicing our or our licensors' inventions in all countries outside the United States, even in jurisdictions where we or our licensors do pursue

patent protection, or from selling or importing products made using our or our licensors' inventions in and into the United States or other jurisdictions. Competitors may use our or our licensors' 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 and our licensors 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 and our licensors' 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 and our licensors' 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 or our licensors 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 technologies and product candidates. While we will endeavor to try to protect our technologies and 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 pending patent applications that we own or the patents or patent applications that we license;
- we or our licensors or future collaborators might not have been the first to make the inventions covered by the pending patent application that we own or have exclusively licensed;
- we or our licensors or future collaborators might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing or otherwise violating our owned or licensed 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 owned or licensed patent applications or those that we may own or license in the future will not lead to issued patents;

- issued patents, if any arise in the future, that we either own or have exclusively licensed may be revoked, modified, or held invalid or unenforceable, as a result of legal challenges by our competitors;
- others may have access to the same intellectual property rights licensed to us in the future on a non-exclusive basis;
- 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 and our licensors' patent applications, including whether the patent applications that we own, presently in-license, or, in the future, in-license will result in issued patents with claims that 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, if they issue in the future, 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 patent applications.

Should any of these or similar events occur, they could significantly harm our business, financial condition, 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 product candidates.

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, misappropriate or otherwise violate existing or future third-party patents or other intellectual property rights. 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 technologies, 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 may be infringed by the manufacture, use or sale of our technologies or product candidates or will prevent, limit or otherwise interfere with our ability to make, use or sell our technologies and 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 and other intellectual property rights 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 or one of our licensing partners 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 or our licensors' 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 or our licensors' 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, insufficient written description or failure to claim patent-eligible subject matter. 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 or our licensors 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 or our licensors' patent claims do not cover the invention, or decide that the other party's use of our or our licensors' 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 or our licensors' patents could limit our ability to assert our or our licensors' 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 position, and our business, financial condition, results of operations and prospects. 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 adversely affect the price of shares of our Class A 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.

Intellectual property rights of third parties could adversely affect our ability to commercialize izokibep, lonigutamab, any of our other product candidates or any future product candidates, and we, our licensors or collaborators, or any future strategic partners may become subject to third party claims or litigation alleging infringement of patents or other proprietary rights or seeking to invalidate patents or other proprietary rights. We might be required to litigate or obtain licenses from third parties in order to develop or market izokibep, lonigutamab, any of our other product candidates or any future product candidates. Such litigation or licenses could be costly or not available on commercially reasonable terms.

Our commercial success depends, in part, on our ability to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property and other proprietary rights of third parties. Third parties may allege that we have infringed, misappropriated or otherwise violated 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 Class A 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 adversely affect 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 product 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, regardless of their merit. We may decide in the future to seek a license to such third-party patents or other intellectual property rights, but we might not be able to do so on reasonable terms. Proving patent 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. As this burden is a high one, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such United States patent or find that our technologies or product candidates do not infringe any such claims. If we are found to infringe, misappropriate or otherwise violate a third party's intellectual property rights, we could be forced, including by court order, to cease developing, manufacturing or commercializing the infringing technology or product candidate. Further, we may be required to redesign the technology or product candidate in a non-infringing manner, which may not be commercially feasible. 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, and it could require us to make substantial licensing and royalty payments. 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 technologies or product candidates or force us to cease some of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on 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 adversely affect 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 European Patent Office (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.

Our product candidates licensed from various third parties may be subject to retained rights.

Our licensors may retain certain rights under the relevant agreements with us, including the right to use the underlying product candidates for academic and research use, to publish general scientific findings from research related to the product candidates, to make customary scientific and scholarly disclosures of information relating to the product candidates, or to develop or commercialize the licensed product candidates in certain regions. It is difficult to monitor whether our licensors limit their use of the product candidates to these uses, and we could incur substantial expenses to enforce our rights to our licensed product candidates in the event of misuse.

In addition, the United States federal government retains certain rights in inventions produced with its financial assistance under the Patent and Trademark Law Amendments Act (Bayh-Dole Act). The federal government retains a "nonexclusive, nontransferable, irrevocable, paid-up license" for its own benefit. The Bayh-Dole Act also provides federal agencies with "march-in rights." March-in rights allow the government, in specified circumstances, to require the contractor or successors in title to the patent to grant a "nonexclusive, partially exclusive, or exclusive license" to a "responsible applicant or applicants." If the patent owner refuses to do so, the government may grant the license itself. We sometimes collaborate with academic institutions to accelerate our preclinical research or development. While it is our policy to avoid engaging university partners in projects in which there is a risk that federal funds may be commingled, we cannot be sure that any co-developed intellectual property will be free from government rights pursuant to the Bayh-Dole Act. If, in the future, we co-own or license in technology which is critical to our business that is developed in whole or in part with federal funds subject to the Bayh-Dole Act, our ability to enforce or otherwise exploit patents covering such technology may be adversely affected.

Changes in patent law in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining, defending, maintaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents, and may diminish our ability to protect our inventions, obtain, maintain, enforce and protect our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our future owned and licensed patents. Patent reform legislation in the United States and other countries, including the Leahy-Smith America Invents Act (Leahy-Smith Act), signed into law on September 16, 2011, could increase those uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our future issued patents. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. 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 or our licensors' patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Thus, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our or our licensors' patent applications and the enforcement or defense of our or our licensors' future issued patents, all of which could adversely affect our business, financial condition, results of operations and prospects.

After March 2013, under the Leahy-Smith Act, the United States transitioned to a first inventor to file system in which, assuming that the other statutory requirements 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 we file an application covering the same invention, could therefore be awarded a patent covering an invention of ours or our licensors even if we had made the invention before it was made by such third party. This will require us to be cognizant going forward 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 or our licensors were the first to either (i) file any patent application related to our product candidates and other proprietary technologies we may develop or (ii) invent any of the inventions claimed in our or our licensors' patents or patent applications. Even where we have a valid and enforceable patent, we may not be able to exclude others from practicing the claimed invention where the other party can show that they used the invention in commerce before our filing date or the other party benefits from a compulsory license. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our future issued patents, all of which could adversely affect our business, financial condition, results of operations and prospects.

In addition, the patent positions of companies in the development and commercialization of pharmaceuticals are particularly uncertain. The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our or our licensors' ability to obtain new patents and patents that we or our licensors might obtain in the future. We cannot predict how future decisions by the courts, the U.S. Congress or the USPTO may impact the value of our patents. Any similar adverse change in the patent laws of other jurisdictions could also adversely affect our business, financial condition, results of operations and prospects.

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

We may be subject to claims that former employees, collaborators or other third parties have an interest in our or our licensors' 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 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 adversely affect 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 current or future licensors may have relied on third-party consultants or collaborators or on funds from third parties, such as the U.S. government, such that our licensors are not the sole and exclusive owners of the patents we in-licensed. If other third parties have ownership rights or other rights to our in-licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products and technology. This could adversely affect our competitive position, business, financial condition, results of operations, and prospects.

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 adversely affect our business, financial condition, results of operations, and prospects.

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

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional or international patent application filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our products or product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products, including generics or biosimilars. Given the amount of time required for the development, testing and regulatory review of products or new product candidates, patents protecting such products or candidates might expire before or shortly after such products or candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient and continuing rights to exclude others from commercializing products similar or identical to ours.

Obtaining and maintaining 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 as a result of noncompliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and/or applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our owned or licensed patents and patent applications. We rely on our outside counsel or our licensing partners to pay these fees due to U.S. and non-U.S. patent agencies. The USPTO and various non-U.S. government patent agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. We are also dependent on our licensors to take the necessary action to comply with these requirements with respect to our licensed intellectual property. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, 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. In such an event, potential competitors might be able to enter the market and this circumstance could adversely affect our business, financial condition, results of operations and prospects.

If we do not obtain patent term extension for our product candidate, our business may be materially harmed.

Depending upon the timing, duration and specifics of any FDA marketing approval of any of our product candidates, one or more of our or our licensors' issued U.S. patents or issued U.S. patents that we may own in the future may be eligible for limited patent term extension under the Drug Price Competition and Patent Term

Restoration Action of 1984 (Hatch-Waxman Amendments). The Hatch-Waxman Amendments permit a patent extension term (PTE) of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. Similar patent term restoration provisions to compensate for commercialization delay caused by regulatory review are also available in certain foreign jurisdictions, such as in Europe under Supplemental Protection Certificate (SPC). However, we may not be granted any extensions for which we apply because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. In addition, to the extent we wish to pursue patent term extension based on a patent that we in-license from a third party, we would need the cooperation of that third party. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension, or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations and prospects could be materially harmed.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

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 or that we elect not to patent, 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. Additionally, trade secrets can be difficult to protect and some courts inside and outside the United States are less willing or unwilling to protect trade secrets. 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. If our trade secrets are not adequately protected, our business, financial condition, results of operations and prospects could be adversely affected.

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 registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. During trademark registration proceedings, we may receive rejections of our applications by the USPTO or in other foreign jurisdictions. Although we are given an opportunity to respond to such rejections, we may be unable to overcome them. 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, which may not survive such proceedings. Moreover, any name we have proposed to use with our product candidate 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, we 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.

We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. 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. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade names, domain name or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our business, financial condition, results of operations and prospects.

We may be subject to claims asserting that our employees, consultants or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property.

Certain of our employees, consultants or advisors have in the past and may in the future be employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these individuals or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. An inability to incorporate such technologies or features would harm our business and may prevent us from successfully commercializing our technologies or product candidates. In addition, we may lose personnel as a result of such claims and any such litigation or the threat thereof may adversely affect our ability to hire employees or contract with independent contractors. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our technologies, or product candidates, which could adversely affect our business, financial condition, results of operations and prospects. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, we or our licensors may in the future be subject to claims by former employees, consultants or other third parties asserting an ownership right in our owned or licensed patents or patent applications. An adverse determination in any such submission or proceeding may result in loss of exclusivity or freedom to operate 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 technology and therapeutics, without payment to us, or could limit the duration of the patent protection covering our technologies and product candidates. Such challenges may also result in our inability to develop, manufacture or commercialize our technologies and product candidates without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our owned or licensed patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future technologies and product candidates. Any of the foregoing could adversely affect our business, financial condition, results of operations and prospects.

Risks Related to Government Regulation

The regulatory approval process is highly uncertain, and we may be unable to obtain, or may be delayed in obtaining, U.S. or foreign regulatory approval and, as a result, unable to commercialize izokibep, lonigutamab, any of our other product candidates or any future product candidates. Even if we believe our current, or planned clinical trials are successful, regulatory authorities may not agree that they provide adequate data on safety or efficacy.

Izokibep, lonigutamab, any of our other product candidates and any future product candidates are subject to extensive governmental regulations relating to, among other things, research, testing, development, manufacturing, approval, recordkeeping, reporting, labeling, storage, packaging, advertising and promotion, pricing, post-approval monitoring, marketing and distribution of products. Rigorous preclinical studies and clinical trials and an extensive regulatory approval process are required to be completed successfully in the United States and in many foreign jurisdictions before a new product can be marketed. Satisfaction of these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. It is possible that none of our product candidates will obtain the regulatory approvals necessary for us to begin selling them.

Our company has no prior experience in conducting and managing the clinical trials necessary to obtain regulatory approvals, including approval by the FDA. The time required to obtain FDA and other approvals is unpredictable but typically takes many years following the commencement of clinical trials, depending upon the type, complexity and novelty of the product candidate. The standards that the FDA and its foreign counterparts use when regulating us require judgment and can change, which makes it difficult to predict with certainty their application. Any analysis we perform of data from preclinical studies and clinical trials is subject to confirmation and interpretation by regulatory authorities, which could delay, limit or prevent regulatory approval. We may also encounter unexpected delays or increased costs due to new government regulations, for example, from future legislation or administrative action, or from changes in FDA policy during the period of product development, clinical trials and FDA regulatory review. It is impossible to predict whether additional legislative changes will be enacted, or whether FDA or foreign regulations, guidance or interpretations will be changed, or the impact of such changes, if any. Any elongation or de-prioritization of preclinical studies or clinical trials or delay in regulatory review resulting from such disruptions could materially affect the development and study of izokibep, lonigutamab, any of our other product candidates or any future product candidates.

Further, the FDA and its foreign counterparts may respond to any BLA that we may submit by defining requirements that we do not anticipate. Such responses could delay clinical development of izokibep, lonigutamab, any of our other product candidates or any future product candidates.

Any delay or failure in obtaining required approvals could adversely affect our ability to generate revenue from the particular product candidate for which we are seeking approval. Furthermore, any regulatory approval to market a product may be subject to limitations on the approved uses for which we may market the product or on the labeling or other restrictions.

We are also subject to or may in the future become subject to numerous foreign regulatory requirements governing, among other things, the conduct of clinical trials, manufacturing and marketing authorization, pricing and third-party reimbursement. The foreign regulatory approval process varies among countries and may include all of the risks associated with the FDA approval process described above, as well as risks attributable to the satisfaction of local regulations in foreign jurisdictions. Moreover, the time required to obtain approval may differ from that required to obtain FDA approval. FDA approval does not ensure approval by regulatory authorities outside the United States and vice versa. Any delay or failure to obtain U.S. or foreign regulatory approval for a product candidate could have a material and adverse effect on our business, financial condition, results of operations and prospects.

Even if we receive regulatory approval for any of our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal. We may also 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 or our existing or future collaborators obtain for our product candidates may also be subject to limitations on the approved indicated uses for which a product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing and surveillance to monitor the safety and efficacy of the product candidate.

In addition, if the FDA, EMA or a comparable foreign regulatory authority approves any of our product candidates, the manufacturing processes, labeling, packaging, distribution, post-approval monitoring and adverse event reporting, storage, import, export, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. The FDA has significant post-market authority, including the authority to require labeling changes based on new safety information and to require post-market studies or clinical trials to evaluate safety risks related to the use of a product or to require withdrawal of the product from the market. The FDA also has the authority to require a REMS plan after approval, which may impose further requirements or restrictions on the distribution or use of an approved drug. The manufacturing facilities we use to make a future product, if any, will also be subject to periodic review and inspection by the FDA and other regulatory agencies, including for continued compliance with current Good Manufacturing Practices (cGMPs) requirements. The discovery of any new or previously unknown problems with our third-party manufacturers, manufacturing processes or facilities may result in restrictions on the product, manufacturer or facility, including withdrawal of the product from the market. As we expect to rely on third-party manufacturers, we will not have control over compliance with applicable rules and regulations by such manufacturers. Any product promotion and advertising will also be subject to regulatory requirements and continuing regulatory review. The FDA imposes stringent restrictions on manufacturers' communications regarding use of their products. Although clinicians may prescribe products for off-label uses as the FDA and other regulatory agencies do not regulate a physician's choice of drug treatment made in the physician's independent medical judgment, they do restrict promotional communications from companies or their sales force with respect to off-label uses of products. In addition, as we do not intend to conduct head-to-head comparative clinical trials for our product candidates, we will be unable to make comparative claims regarding any other products in the promotional materials for our product candidates. If we promote our products, if approved, in a manner inconsistent with FDA-approved labeling or otherwise not in compliance with FDA regulations, we may be subject to enforcement action. If we or our existing or future collaborators, manufacturers or service providers fail to comply with applicable continuing regulatory requirements in the United States or foreign jurisdictions in which we seek to market our product candidates, we or they may be subject to, among other things, fines, warning or untitled letters, holds on clinical trials, delay of approval or refusal by the FDA or similar foreign regulatory bodies to approve pending applications or supplements to approved applications, suspension or withdrawal of regulatory approval, product recalls and seizures, administrative detention of products, refusal to permit the import or export of products, operating restrictions, injunction, civil penalties and criminal prosecution.

Subsequent discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or 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 or manufacturing of the product, withdrawal of the product from the market or voluntary or mandatory product recalls;
- fines, warning or untitled letters or holds on clinical trials;
- refusal by the Medicines and Healthcare Products Regulatory Agency or the FDA to approve pending applications or supplements to approved applications filed by us or our strategic partners;
- suspension or revocation of product license approvals;

- product seizure or detention or refusal to permit the import or export of products; and
- injunctions or the imposition of civil or criminal penalties.

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. Changes in FDA staffing could result in delays in the FDA's responsiveness or in its ability to review submissions or applications, issue regulations or guidance, or implement or enforce regulatory requirements in a timely fashion or at all.

Recently enacted legislation, future legislation and other healthcare reform measures may increase the difficulty and cost for us to obtain marketing approval for and commercialize our product candidates and may affect the prices we may set.

In the United States and some foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system, including cost-containment measures that may reduce or limit coverage and reimbursement for newly approved drugs and affect our ability to profitably sell any product candidates for which we obtain marketing approval. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare.

For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the ACA) was enacted in the United States, which substantially changed the way healthcare is financed by both governmental and private insurers in the United States and significantly affected the pharmaceutical industry. The ACA, among other things, subjected biologic products to potential competition by lower-cost biosimilars, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program (MDRP) are calculated for drugs and biologics that are inhaled, infused, instilled, implanted or injected, increased the minimum Medicaid rebates owed by manufacturers under the MDRP, extended manufacturer Medicaid rebate obligations to utilization by individuals enrolled in Medicaid managed care organizations, established annual fees and taxes on manufacturers of certain branded prescription drugs and biologics, and established a new Medicare Part D coverage gap discount program. Since its enactment, there have been judicial, congressional, and executive branch challenges to the ACA, which have resulted in delays in the implementation of, and action taken to repeal or replace, certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. In addition, there have been a number of health reform initiatives by the Biden administration that have impacted the ACA. For example, on August 16, 2022, President Biden signed the IRA, into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and through a newly established manufacturer discount program. It is possible that the ACA will be subject to judicial or congressional challenges in the future. It is unclear how other such challenges, and the healthcare reform measures of the Biden administration will impact the ACA and our business.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. For example, on August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, resulted in reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2031, with the exception of a temporary suspension from May 1, 2020 through March 31, 2021, unless additional Congressional action is taken. Under current legislation, the actual reduction in Medicare payments will vary from 1% in 2022 to up to 4% in the final fiscal year of this sequester.

Further, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs. Such scrutiny has resulted in several recent

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 products. For example, in July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, the U.S. Department of Health and Human Services (HHS) released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. In addition, the IRA, among other things, (1) directs HHS to negotiate the price of certain single-source drugs and biologics covered under Medicare and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions will take effect progressively starting in fiscal year 2023, although they may be subject to legal challenges. Further, the Biden administration released an additional executive order on October 14, 2022, directing HHS to submit a report within 90 days on how the Center for Medicare and Medicaid Innovation can be further leveraged to test new models for lowering drug costs for Medicare and Medicaid beneficiaries. Moreover, the American Taxpayer Relief Act of 2021, effective January 1, 2024, would eliminate the statutory cap on rebate amounts owed by drug manufacturers under the MDRP, which is currently capped at 100% of the Average Manufacturer Price (AMP) for a covered outpatient drug.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological 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. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, financial condition, results of operations and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our product candidates, if approved, or put pressure on our product pricing, which could negatively affect our business, financial condition, results of operations and prospects.

We expect that the ACA, the IRA, and any other healthcare reform measures that may be adopted in the future may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government 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, if approved.

Our current product candidates and any of our future product candidates regulated as biologics in the United States may face competition sooner than anticipated from biosimilars approved through an abbreviated regulatory pathway.

The enactment of the Biologics Price Competition and Innovation Act of 2009 (BPCIA) as part of the Patient ACA created an abbreviated pathway for the approval of biosimilar and interchangeable biological products. The abbreviated regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biological products, including the possible designation of a biosimilar as "interchangeable" based on its similarity to an existing brand product. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the original branded product was approved under a BLA. Certain changes, however, and supplements to an approved BLA, and subsequent applications filed by the same sponsor, manufacturer, licensor, predecessor in interest, or other related entity do not qualify for the 12-year exclusivity period.

Our product candidates are all biological product candidates. We anticipate being awarded market exclusivity for each of our biological product candidates that is subject to its own BLA for 12 years in the United

States. However, the term of the patents that cover such product candidates may not extend beyond the applicable market exclusivity awarded by a particular country. For example, in the United States, if all of the patents that cover our particular biological product expire before the 12-year market exclusivity expires, a third party could submit a marketing application for a biosimilar product four years after approval of our biological product, the FDA could immediately review the application and approve the biosimilar product for marketing 12 years after approval of our biological product, and the biosimilar sponsor could then immediately begin marketing. Alternatively, a third party could submit a full BLA for a similar or identical product any time after approval of our biological product, and the FDA could immediately review and approve the similar or identical product for marketing and the third party could begin marketing the similar or identical product upon expiry of all of the patents that cover our particular biological product.

There is also a risk that this exclusivity could be changed in the future. For example, this exclusivity could be shortened due to congressional action or through other actions, including future proposed budgets, international trade agreements and other arrangements or proposals. Additionally, there is a risk that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for biosimilar competition sooner than anticipated. The extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. It is also possible that payors will give reimbursement preference to biosimilars over reference biological products, even absent a determination of interchangeability.

Laws and regulations outside the United States differ, including the length and extent of patent and exclusivity protection and pathways for competition to enter the market. For example, in the EU exclusivity is generally 10 years and can be extended to 11 years under certain circumstances. Other countries may have significantly shorter or longer periods of exclusivity. In addition, other countries may have different standards in determining similarity to a reference product. Any market entry of competing products to our product candidates in these other regions could adversely affect our business in those regions.

To the extent that we do not receive any anticipated periods of regulatory exclusivity for our product candidates it could adversely affect our business, financial condition, results of operations and prospects.

Our operations and relationships with healthcare providers, healthcare organizations, customers and third-party payors will be subject to applicable anti-bribery, anti-kickback, fraud and abuse, transparency and other healthcare and privacy laws and regulations, which could expose us to, among other things, enforcement actions, criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings.

Our future arrangements with healthcare providers, healthcare organizations, third-party payors and customers will expose us to broadly applicable anti-bribery, fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we research, market, sell and distribute our products, if approved. In addition, we may be subject to data privacy and security regulation by the U.S. federal government and the states and the foreign governments in which we conduct our business. Restrictions under applicable federal and state anti-bribery and healthcare laws and regulations, include the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, individuals and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made, in whole or in part, under a federal and state healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- the federal criminal and civil false claims laws, including the federal False Claims Act, which can be enforced through civil whistleblower or qui tam actions against individuals or entities, and the Federal Civil Monetary Penalties Laws, which prohibit, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, certain marketing practices, including off-label promotion, may also violate false claims laws. Moreover, the government may assert that a claim including items and services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act;
- Health Insurance Portability and Accountability Act (HIPAA), which imposes criminal and civil liability, prohibits, among other things, knowingly and willfully executing, or attempting to execute a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services; similar to the federal Anti- Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH) and their respective implementing regulations, which impose obligations on certain healthcare providers, health plans, and healthcare clearinghouses, known as covered entities, as well as their business associates that perform certain services involving the storage, use or disclosure of individually identifiable health information for or on behalf of a covered entity and their covered subcontractors, including mandatory contractual terms, with respect to safeguarding the privacy, security, and transmission of individually identifiable health information, and require notification to affected individuals and regulatory authorities of certain breaches of security of individually identifiable health information;
- the federal legislation commonly referred to as the Physician Payments Sunshine Act, enacted as part of the ACA, and its implementing regulations, which requires certain manufacturers of covered drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program, with certain exceptions, to report annually to the Centers for Medicare & Medicaid Services (CMS) information on certain payments and other transfers of value to clinicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), teaching hospitals, and certain other health care providers (such as physician assistants and nurse practitioners), as well as ownership and investment interests held by the clinicians described above and their immediate family members;
- state privacy laws and regulations that impose restrictive requirements regulating the use and disclosure of personal information, including health information;
- foreign privacy, data protection, and data security laws and regulations, such as the European Union's General Data Protection Regulation (EU GDPR), which imposes comprehensive obligations on covered businesses to, among other things, make contractual privacy, data protection and data security commitments, cooperate with European data protection authorities, implement security measures, give data breach notifications, and keep records of personal information processing activities;
- the U.S. Foreign Corrupt Practices Act of 1977, as amended, which prohibits, among other things, U.S. companies and their employees and agents from authorizing, promising, offering, or providing, directly or indirectly, corrupt or improper payments or anything else of value to foreign government officials, employees of public international organizations and foreign government owned or affiliated entities, candidates for foreign political office, and foreign political parties or officials thereof;
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, that may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; and

- certain 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 in addition to requiring drug manufacturers to report information related to payments to clinicians and other healthcare providers or marketing expenditures and drug pricing information, and state and local laws that require the registration of pharmaceutical sales representatives.

If we or our current or future collaborators, manufacturers or service providers fail to comply with applicable federal, state or foreign laws or regulations, we could be subject to enforcement actions, which could affect our ability to develop, market and sell our product candidates successfully and could harm our reputation and lead to reduced acceptance of our products, if approved by the market.

Efforts to ensure that our current and future business arrangements with third parties comply with applicable healthcare laws and regulations could involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any such requirements, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, the curtailment or restructuring of our operations, loss of eligibility to obtain approvals from the FDA, exclusion from participation in government contracting, healthcare reimbursement or other government programs, including Medicare and Medicaid, integrity oversight and reporting obligations, or reputational harm, any of which could adversely affect our financial results. These risks cannot be entirely eliminated. Any action against us for an alleged or suspected violation could cause us to incur significant legal expenses and could divert our management's attention from the operation of our business, even if our defense is successful. In addition, achieving and sustaining compliance with applicable laws and regulations may be costly to us in terms of money, time and resources.

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

In some countries, particularly in the European Union, 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 drug. 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. In addition, many countries outside the U.S. have limited government support programs that provide for reimbursement of drugs such as our product candidates, with an emphasis on private payors for access to commercial products. If reimbursement of our products, if approved is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be materially harmed.

We are subject to stringent and evolving U.S. and foreign laws, regulations, rules, contractual obligations, and policies related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse business consequences.

In the ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, process or processing) personal data and other sensitive information, including proprietary and confidential business data, trade secrets, employee data, intellectual property, data we collect about trial participants in connection with clinical trials, and other sensitive third-party data (collectively, sensitive data). Our data processing activities may subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements, and other obligations relating to data privacy and security.

Various federal, state, local and foreign legislative and regulatory bodies, or self-regulatory organizations, may expand current laws, rules or regulations, enact new laws, rules or regulations or issue revised rules or guidance regarding data privacy and security. In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), and other similar laws (e.g., wiretapping laws). For example, HIPAA, as amended by HITECH, imposes specific requirements relating to the privacy, security, and transmission of individually identifiable health information. Additionally, the California Consumer Privacy Act (CCPA) applies to personal information of consumers, business representatives, and employees, and among other things requires businesses to provide specific disclosures in privacy notices and honor requests of California residents to exercise certain privacy rights, including the right to opt out of certain disclosures of their information. The CCPA provides for civil penalties of up to $7,500 per violation 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, the CCPA may impact our processing of personal information and increases our compliance costs. Additionally, the California Privacy Rights Act of 2020 (CPRA) significantly expands the CCPA, such as granting additional rights to California residents, including the right to correct personal information and additional opt-out rights. The CPRA also establishes a regulatory agency dedicated to enforcing the CCPA and the CPRA. Other states, such as Virginia, Connecticut, Utah and Colorado, have also passed comprehensive privacy laws, and similar laws are being considered in several other states, as well as at the federal and local levels. While these state privacy laws, like the CCPA, also exempt some data processed in the context of clinical trials, these developments further complicate compliance efforts, and increase legal risk and compliance costs for us and the third parties upon whom we rely. In addition to government activity, privacy advocacy groups and technology and other industries are considering various new, additional or different self-regulatory standards that may place additional burdens on us.

There are also various laws and regulations in other jurisdictions outside the United States relating to data privacy and security, with which we may need to comply. For example, the EU GDPR and the United Kingdom's equivalent (UK GDPR), collectively, GDPR, impose strict requirements for processing personal data. We also have operations in Asia, and may be subject to new and emerging data privacy regimes such as Japan's Act on the Protection of Personal Information. Notably, the EU GDPR and UK GDPR impose large penalties for noncompliance, including the potential for fines of up to €20 million under the EU GDPR / £17.5 million under the UK GDPR, or 4% of the annual global revenue of the noncompliant entity, whichever is greater. The EU GDPR and UK GDPR also provide for private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests. Additionally, EU member states may introduce further conditions, including limitations, and make their own laws and regulations further limiting the processing of 'special categories of personal data, including personal data related to health, biometric data used for unique identification purposes and genetic information, which could limit our ability to collect, use and share EU data, and could cause our compliance costs to increase, ultimately adversely affecting our business, financial condition, results of operations and prospects.

In addition, we may be unable to transfer personal data from Europe and other jurisdictions to the United States or other countries due to data localization requirements or limitations on cross-border data flows. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the European Economic Area (EEA) and the UK have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it believes are inadequate.

Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA and UK's standard contractual clauses, these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. If there is no lawful manner for us to transfer personal data from the EEA, the UK or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences,

including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activist groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers out of Europe for allegedly violating the EU GDPR's cross-border data transfer limitations.

In addition to data privacy and security laws, we are also bound by other contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful.

Each of these laws, rules, regulations and contractual obligations relating to data privacy and security, and any other such changes or new laws, rules, regulations or contractual obligations could impose significant limitations, require changes to our business, or restrict our collection, use, storage or processing of personal information, which may increase our compliance expenses and make our business more costly or less efficient to conduct. In addition, any such changes could compromise our ability to develop an adequate marketing strategy and pursue our growth strategy effectively or even prevent us from providing certain products in jurisdictions in which we currently operate and in which we may operate in the future or incur potential liability in an effort to comply with such legislation, which, in turn, could adversely affect our business, financial condition, results of operations and prospects. Complying with these numerous, complex and often changing regulations is expensive and difficult, and failure to comply with any data privacy or security laws, whether by us, one of our CROs, CMOs or business associates or another third party, could adversely affect our business, financial condition, results of operations and prospects, 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, EU GDPR and UK GDPR have 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, EU GDPR and UK 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 EEA and other jurisdictions, and we cannot determine the impact such future laws, regulations and standards may have on our business.

Any actual or perceived failure by us or our third-party service providers to comply with any federal, state or foreign laws, rules, regulations, industry self-regulatory principles, industry standards or codes of conduct, regulatory guidance, orders to which we may be subject or other legal obligations relating to privacy, data protection, data security or consumer protection could adversely affect our reputation, brand and business. We may also be contractually required to indemnify and hold harmless third parties from the costs or consequences of non-compliance with any laws, rules and regulations or other legal obligations relating to privacy or any inadvertent or unauthorized use or disclosure of data that we store or handle as part of operating our business. Any of these events could adversely affect our reputation, business, or financial condition, including but not limited to: loss of customers; interruptions or stoppages in our business operations (including clinical trials); inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our business model or operations.

We cannot assure you that our CROs, CMOs or other third-party service providers with access to our or our suppliers', manufacturers', trial participants' and employees' sensitive information in relation to which we are

responsible will not breach contractual obligations imposed by us, or that they will not experience data security incidents, 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, financial condition, results of operations and prospects. 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 adversely affect our business, financial condition, results of operations and prospects.

We also publicly post our privacy policies and practices concerning our collection, use, disclosure and other processing of the personal information provided to us by our website visitors and by our customers. Although we endeavor to comply with our public statements and documentation, we may at times fail to do so or be perceived to have failed to do so. Our publication of our privacy policies and other statements we publish that provide promises and assurances about privacy and security can subject us to potential state and federal action if they are found to be deceptive, unfair or misrepresentative of our actual practices. Any actual or perceived failure by us to comply with federal, state or foreign laws, rules or regulations, industry standards, contractual or other legal obligations, or any actual, perceived or suspected cybersecurity incident, whether or not resulting in unauthorized access to, or acquisition, release or transfer of personal information or other data, may result in enforcement actions and prosecutions, private litigation, significant fines, penalties and censure, claims for damages by customers and other affected individuals, regulatory inquiries and investigations or adverse publicity and could cause our customers to lose trust in us, any of which could adversely affect our business, financial condition, results of operations and prospects.

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.

Risks Related to Our Reliance on Third Parties

We may have conflicts with our current or future licensors or collaborators that could delay or prevent the development or commercialization of our product candidates.

We are currently party to license and collaboration agreements with Affibody and Pierre Fabre, and we expect to enter into similar strategic transactions in the future. We may have conflicts with our current or future collaborators, such as conflicts concerning the interpretation of preclinical or clinical data, the achievement of milestones, the interpretation of contractual obligations, payments for services, development obligations or the ownership of intellectual property developed during our collaboration. If any conflicts arise with any of our collaborators, such collaborator may act in a manner that is adverse to our best interests. Any such disagreement could result in one or more of the following, each of which could delay or prevent the development or commercialization of our product candidates, and in turn prevent us from generating revenue: disputes regarding milestone payments or royalties; uncertainty regarding ownership of intellectual property rights arising from our collaborative activities, which could prevent us from entering into additional collaborations; unwillingness by the collaborator to cooperate in the development or manufacture of a product candidate, including providing us with data or materials; unwillingness on the part of a collaborator to keep us informed regarding the progress of its development and commercialization activities or to permit public disclosure of the results of those activities; initiating of litigation or alternative dispute resolution options by either party to resolve the dispute; or attempts by either party to terminate the agreement.

We have relied and expect to continue to rely on third parties to conduct our preclinical studies and clinical trials. If those third parties do not perform as contractually required, fail to satisfy legal or regulatory requirements, miss expected deadlines or terminate the relationship, our development programs could be delayed, more costly or unsuccessful, and we may never be able to seek or obtain regulatory approval for or commercialize our product candidates.

We rely and intend to rely in the future on third-party clinical investigators, CROs, clinical data management organizations to conduct, supervise and monitor preclinical studies and clinical trials of our current or future product candidates. Because we currently rely and intend to continue to rely on these third parties, we will have less control over the timing, quality and other aspects of preclinical studies and clinical trials than we would have had we conducted them independently. These parties are not, and will not be, our employees and we will have limited control over the amount of time and resources that they dedicate to our programs. Additionally, such parties may have contractual relationships with other entities, some of which may be our competitors, which may draw time and resources from our programs.

We 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 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, partners or consultants. Relying on third-party clinical investigators or CROs 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 participants treated with products from these different facilities, in our product registrations. Further, our third party clinical manufacturers 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 preclinical studies are conducted in accordance with good laboratory practices (GLPs) and clinical trials are conducted in accordance with GCPs. Moreover, the FDA and comparable foreign regulatory authorities require us to comply with 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 a BLA is submitted to the FDA) of trial sponsors, clinical investigators, trial sites and certain third parties including 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. 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.

In the event we need to repeat, extend, delay or terminate our clinical trials because 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, our clinical trials may need to be repeated,

extended, delayed or terminated and 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 revenue 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.

In addition, 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 rely on third-party manufacturers and suppliers to supply our product candidates. The loss of our third-party manufacturers or suppliers, or their failure to comply with applicable regulatory requirements or to supply sufficient quantities at acceptable quality levels or prices, within acceptable timeframes, or at all, would materially and adversely affect our business.

We do not own or operate facilities for drug manufacturing, storage, distribution or quality testing. We currently rely, and expect to continue to rely, on third-party contract developers and manufacturers, including in Europe and, for lonigutimab, in China, to manufacture bulk drug substances, drug products, raw materials, samples, components, and other materials for our product candidates. Reliance on third-party manufacturers may expose us to different risks than if we were to manufacture product candidates ourselves. There can be no assurance that our preclinical and clinical development product supplies will not be limited, interrupted, terminated or will be of satisfactory quality or be available at acceptable prices. In addition, any replacement of our manufacturer could require significant effort and time because there may be a limited number of qualified replacements.

The manufacturing process for our product candidates is subject to the FDA, EMA and foreign regulatory authority review. We, and our suppliers and manufacturers, some of which are currently our sole source of supply, must meet applicable manufacturing requirements and undergo rigorous facility and process validation tests required by regulatory authorities in order to comply with regulatory standards, such as cGMPs. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the FDA, EMA and foreign regulatory authorities. If our CMOs cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA, EMA or comparable foreign regulatory authorities, we may not be able to rely on their facilities for the manufacture of elements of our product candidates. Moreover, we do not conduct the manufacturing process ourselves and are dependent on our CMOs for manufacturing in compliance with current regulatory

requirements. In the event that any of our manufacturers fails to comply with such requirements or to perform its obligations in relation to quality, timing or otherwise, or if our projected manufacturing capacity or supply of materials becomes limited, interrupted, or more costly than anticipated, we may be forced to enter into an agreement with another third party, which we may not be able to do timely or on reasonable terms, if at all. In some cases, the technical skills or technology required to manufacture our product candidates may be unique or proprietary to the original manufacturer and we may have difficulty transferring such to another third party.

These factors would increase our reliance on such manufacturer or require us to obtain a license from such manufacturer in order to enable us, or to have another third party, manufacture our product candidates. If we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with applicable quality standards and regulations and guidelines; and we may be required to repeat some of the development program. The delays and costs associated with the verification of a new manufacturer could negatively affect our ability to develop product candidates in a timely manner or within budget.

We expect to continue to rely on third-party manufacturers if we receive regulatory approval for any product candidate. To the extent that we have existing, or enter into future, manufacturing arrangements with third parties, we will depend on these third parties to perform their obligations in a timely manner consistent with contractual and regulatory requirements, including those related to quality control and assurance. Any manufacturing facilities used to produce our product candidates will be subject to periodic review and inspection by the FDA and foreign regulatory authorities, including for continued compliance with cGMP requirements, quality control, quality assurance and corresponding maintenance of records and documents. If we are unable to obtain or maintain third-party manufacturing for product candidates, or to do so on commercially reasonable terms, we may not be able to develop and commercialize our product candidates successfully. Our or a third party's failure to execute on our manufacturing requirements, comply with cGMPs or maintain a compliance status acceptable to the FDA, EMA or foreign regulatory authorities could adversely affect our business in a number of ways, including:

- an inability to initiate or continue preclinical studies or clinical trials of product candidates;
- delay in submitting regulatory applications, or receiving regulatory approvals, for product candidates;
- loss of the cooperation of existing or future collaborators;
- requirements to cease distribution or to recall batches of our product candidates; and
- in the event of approval to market and commercialize a product candidate, an inability to meet commercial demands for our products.

Additionally, our CMOs may experience difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If our CMOs were to encounter any of these difficulties, our ability to provide our product candidates to participants in preclinical and clinical trials, or to provide product for treatment of participants once approved, would be jeopardized.

We depend on sole source and limited source suppliers for certain drug substances, drug products, raw materials, samples, components, and other materials used in our product candidates. If we are unable to source these supplies on a timely basis, or establish longer-term contracts with our CMOs, we will not be able to complete our clinical trials on time and the development of our product candidates may be delayed.

We depend on sole source and limited source suppliers for certain drug substances, drug products, raw materials, samples, components, and other materials used in our product candidates. We do not currently have long-term supply contracts with all of our CMOs and they are not obligated to supply drug products to us for any period, in any specified quantity or at any certain price beyond the delivery contemplated by the relevant

purchase orders. As a result, our suppliers could stop selling to us at commercially reasonable prices, or at all. While we intend to enter into long-term master supply agreements with certain of our CMOs in the future as we advance our clinical trials or commercialization plans, we may not be successful in negotiating such agreements on favorable terms or at all. If we do enter into such long-term master supply agreements, or enter into such agreements on less favorable terms than we currently have with such manufacturers, we could be subject to binding long-term purchase obligations that may be harmful to our business, including in the event that we do not conduct our trials on planned timelines or utilize the drug products that we are required to purchase. Any change in our relationships with our CMOs or changes to contractual terms of our agreements with them could adversely affect our business, financial condition, results of operations and prospects.

Furthermore, any of the sole source and limited source suppliers upon whom we rely could stop producing our supplies, cease operations or be acquired by, or enter into exclusive arrangements with, our competitors. Additionally, our manufacturing process for izokibep requires special equipment, and identifying additional suppliers able to fabricate such equipment at their facility at acceptable costs may be difficult. Establishing additional or replacement suppliers for these supplies, and obtaining regulatory clearance or approvals that may result from adding or replacing suppliers, could take a substantial amount of time, result in increased costs and impair our ability to produce our products, which would adversely impact our business, financial condition, results of operations and prospects. Any such interruption or delay may force us to seek similar supplies from alternative sources, which may not be available at reasonable prices, or at all. Any interruption in the supply of sole source or limited source components for our product candidates would adversely affect our ability to meet scheduled timelines and budget for the development and commercialization of our product candidates, could result in higher expenses and would harm our business. Although we have not experienced any significant disruption as a result of our reliance on limited or sole source suppliers, we have a limited operating history and cannot assure you that we will not experience disruptions in our supply chain in the future as a result of such reliance or otherwise.

The operations of our suppliers, most of which are located outside of the United States, are subject to additional risks that are beyond our control and that could harm our business, financial condition, results of operations and prospects.

Currently, most of our suppliers are located outside of the United States. As a result of our global suppliers, we are subject to risks associated with doing business abroad, including:

- political unrest, terrorism, labor disputes, and economic instability resulting in the disruption of trade from foreign countries in which our products are manufactured;
- the imposition of new laws and regulations, including those relating to labor conditions, quality, and safety standards, imports, duties, taxes, and other charges on imports, as well as trade restrictions and restrictions on currency exchange or the transfer of funds, particularly new or increased tariffs imposed on imports from countries where our suppliers operate;
- greater challenges and increased costs with enforcing and periodically auditing or reviewing our suppliers' and manufacturers' compliance with cGMPs or status acceptable to the FDA, EMA or foreign regulatory authorities;
- reduced protection for intellectual property rights, including trademark protection, in some countries, particularly China;
- disruptions in operations due to global, regional, or local public health crises or other emergencies or natural disasters, including, for example, disruptions due to the ongoing COVID-19 pandemic given the emergence of new variants and disparities in availability of vaccines in different parts of the world;
- disruptions or delays in shipments; and
- changes in local economic conditions in countries where our manufacturers or suppliers are located.

These and other factors beyond our control, particularly in light of the COVID-19 pandemic or any comparable pandemic, could interrupt our suppliers' production, influence the ability of our suppliers to export our clinical supplies cost-effectively or at all, and inhibit our suppliers' ability to procure certain materials, any of which could harm our business, financial condition, results of operations and prospects.

The manufacturing of our product candidates is complex, and our third-party manufacturers may encounter difficulties in production. If our third-party manufacturers encounter such difficulties, our ability to provide supply of our product candidates for clinical trials, our ability to obtain marketing approval, or provide supply of our products for participants, if approved, could be delayed or halted.

Our product candidates are biopharmaceuticals and the process of manufacturing biopharmaceuticals is complex, time-consuming, highly regulated and subject to multiple risks. Our CMOs must comply with legal requirements, cGMPs and guidelines for the manufacturing of biopharmaceuticals used in clinical trials and, if approved, marketed products. Our CMOs may have limited experience in the manufacturing of cGMP batches of our products.

Manufacturing biopharmaceuticals is highly susceptible to drug product loss due to contamination, equipment failure, improper installation or operation of equipment, vendor or operator error, inconsistency in yields, variability in product characteristics and difficulties in scaling the production process. If any such drug product loss occurs, the impact to our business could be compounded by the long lead times needed to procure additional drug product due to plant capacity limitations, or other restrictions, at our CMOs. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If microbial, viral or other contaminations are discovered at our third-party manufacturers' facilities, such facilities may need to be closed for an extended period of time to investigate and remedy the contamination, which could delay clinical trials and adversely affect our business. Moreover, if the FDA, EMA or any other regulatory authority determines that our third-party manufacturers' facilities are not in compliance with applicable laws and regulations, including those governing cGMPs, they may deny BLA establishment licensure until the deficiencies are corrected or we replace the manufacturer in our BLA with a manufacturer that is able to ensure safety, purity and potency of the product being manufactured.

In addition, there are risks associated with large scale manufacturing for clinical trials or commercial scale including, among others, cost overruns, potential problems with process scale-up, process reproducibility, stability issues, compliance with cGMPs, lot consistency and timely availability of raw materials. Even if we obtain regulatory approval for any of our product candidates, there is no assurance that manufacturers will be able to manufacture the approved product to specifications acceptable to the FDA, EMA 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. If our manufacturers are unable to produce sufficient quantities for clinical trials or for commercialization, commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and prospects.

Scaling up a biopharmaceutical manufacturing process is a difficult and uncertain task. If our third-party manufacturers are unable, or decide not, to adequately validate or scale-up the manufacturing process at our current manufacturers' facilities, we will need to transfer to another manufacturer and complete the manufacturing validation process, which can be lengthy. If we are able to adequately validate and scale-up the manufacturing process for our product candidates with a CMOs, we will in most cases still need to negotiate with such CMOs an agreement for commercial supply and it is not certain we will be able to come to agreement on terms acceptable to us.

We cannot assure you that any stability or other issues relating to the manufacture of any of our current or future product candidates or products will not occur in the future. If our third-party manufacturers were to encounter any of these difficulties, our ability to provide any product candidates to participants in clinical trials and products to participants, once approved, would be jeopardized. Any delay or interruption in clinical trial

supplies could delay the completion of planned clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials completely. Any adverse developments affecting clinical or commercial manufacturing of our product candidates or products may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls, or other interruptions in the supply of our product candidates or products. We may also have to take inventory write-offs and incur other charges and expenses for product candidates or products that fail to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives. Accordingly, failures or difficulties faced at any level of our supply chain could adversely affect our business and delay or impede the development and commercialization of any of our product candidates or products, if approved, and could have an adverse effect on our business, financial condition, results of operations and prospects.

As part of our process development efforts, we also may make changes to the manufacturing processes at various points during development, for various reasons, such as controlling costs, achieving scale, decreasing processing time, increasing manufacturing success rate or other reasons. Such changes carry the risk that they will not achieve their intended objectives, and any of these changes could cause our current or future product candidates to perform differently and affect the results of our future clinical trials. In some circumstances, changes in the manufacturing process may require us to perform *ex vivo* comparability studies and to collect additional data from participants prior to undertaking more advanced clinical trials. For instance, changes in our process during the course of clinical development may require us to show the comparability of the product used in earlier clinical phases or at earlier portions of a trial to the product used in later clinical phases or later portions of the trial.

Risks Related to this Offering and Ownership of Our Class A Common Stock

An active and liquid trading market for our Class A Common Stock may not develop and you may not be able to resell your shares of Class A Common Stock at or above the public offering price, if at all.

Prior to this offering, no market for shares of our Class A Common Stock existed. We intend to apply to list our Class A Common Stock on Nasdaq under the symbol "XLRN." Assuming that our Class A Common Stock is listed and after the consummation of this offering, an active or liquid trading market for our Class A Common Stock may never develop or be sustained following this offering. To the extent certain of our existing stockholders and their affiliated entities participate in this offering, such purchases would reduce the non-affiliated public float of our shares, meaning the number of shares of our Class A Common Stock that are not held by officers, directors and affiliated stockholders. A reduction in the public float could reduce the number of shares that are available to be traded at any given time, thereby adversely impacting the liquidity of our Class A Common Stock and depressing the price at which you may be able to sell your shares. Moreover, the initial public offering price for our Class A Common Stock will be determined through negotiations with the underwriters, and may vary from the market price of our Class A Common Stock following this offering. As a result of these and other factors, you may be unable to resell your shares of our Class A Common Stock at or above the initial public offering price, at the time you wish to sell them, or at a price that you consider reasonable. The lack of an active market may also reduce the fair market value of your shares. Furthermore, an inactive market may also impair our ability to raise capital by selling shares of our Class A Common Stock in the future, and may impair our ability to enter into strategic collaborations or acquire companies or products by using our shares of Class A Common Stock as consideration.

Our quarterly and annual operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts or any guidance we may publicly provide, each of which may cause our stock price to fluctuate or decline.

We expect our operating results to be subject to quarterly and annual fluctuations which may, in turn, cause the price of our Class A Common Stock to fluctuate substantially. Our net loss and other operating results will be affected by numerous factors, including:

- variations in the level of expense related to the ongoing development of izokibep, lonigutamab, and our other product candidates or future development programs;
- results and timing of preclinical studies and ongoing and future clinical trials, or the addition or termination of any such clinical trials;
- the timing of payments we may make or receive under existing license and collaboration arrangements or the termination or modification thereof;
- our execution of any strategic transactions, including acquisitions, collaborations, licenses or similar arrangements, and the timing and amount of payments we may make or receive in connection with such transactions;
- any intellectual property infringement lawsuit or opposition, interference or cancellation proceeding in which we may become involved;
- recruitment and departures of key personnel;
- if any of our product candidates receives regulatory approval, the terms of such approval and market acceptance and demand for such products;
- regulatory developments affecting our product candidates or those of our competitors;
- the continuing effect of the COVID-19 pandemic and the impacts of inflation and rising interest rates on our business and operations; and
- changes in general market and economic conditions.

If our quarterly or annual operating results fall below the expectations of investors or securities analysts or any forecasts or guidance we may provide to the market, the price of our Class A Common Stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated guidance we may provide. We believe that quarterly or annual comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

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

The market price of our Class A 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 and capital markets due to the COVID-19 pandemic or otherwise;
- announcements relating to our product candidates, including the results of clinical trials by us or our collaborators;
- announcements by competitors that impact our competitive outlook;
- negative developments with respect to our product candidates, or similar products or product candidates with which we compete;
- developments with respect to patents or intellectual property rights;

- announcements of technological innovations, new product candidates, new products or new contracts by us or our competitors;
- announcements relating to strategic transactions, including acquisitions, collaborations, licenses or similar arrangements;
- 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 (or losses) meet or exceed such estimates;
- announcement or expectation of additional financing efforts and receipt, or lack of receipt, of funding in support of conducting our business;
- sales of our Class A Common Stock by us, our insiders, or other stockholders, or issuances by us of shares of our Class A Common Stock in connection with strategic transactions;
- expiration of market standoff or lock-up agreements described in the section titled "Underwriters" section;
- conditions and trends in the pharmaceutical, biotechnology and other industries;
- regulatory developments within, and outside of, the United States, including changes in the structure of health care payment systems;
- litigation or arbitration;
- COVID-19 or other pandemics, 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 section titled "Risk Factors".

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 Class A 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.

You will experience immediate and substantial dilution as a result of this offering and may experience additional dilution in the future.

You will suffer immediate and substantial dilution with respect to the Class A Common Stock you purchase in this offering. Specifically, assuming an initial public offering price of $ per share, which is the midpoint of the estimated price range set forth on the cover page of this prospectus, and assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and that the underwriters do not exercise their over-allotment option to purchase additional shares of Class A Common Stock in this offering, you will incur immediate dilution of $ per share. That number represents the difference between the assumed initial public offering price of $ per share and our pro forma net tangible book value per share as of March 31, 2023, after giving effect to (i) this offering, (ii) the automatic conversion of all outstanding shares of our convertible redeemable preferred stock into an equivalent number of shares of Class A Common Stock upon the completion of this offering, and (iii) the issuance of shares of our Class A Common Stock upon the vesting and settlement of RSUs upon the completion of this offering.

For a further description of the dilution you will experience immediately after this offering, see the section titled "Dilution."

Sales of a substantial number of shares of our Class A Common Stock by our existing stockholders in the public market could cause our stock price to fall.

Sales of a substantial number of shares of our Class A Common Stock in the public market or the perception that these sales might occur could significantly reduce the market price of our Class A Common Stock and impair our ability to raise adequate capital through the sale of additional equity securities.

Based on shares of Class A Common Stock outstanding as of March 31, 2023, upon the closing of this offering, we will have outstanding a total of shares of Class A Common Stock, assuming no exercise of the underwriters' option to purchase additional shares and no exercise of outstanding options or restricted stock units subsequent to such date. Of these shares, only the shares of Class A Common Stock sold in this offering by us, plus any shares sold upon exercise of the underwriters' option to purchase additional shares, will (unless they are purchased by one of our affiliates) be freely tradable, without restriction, in the public market immediately following this offering.

Our directors and executive officers and holders of substantially all of our outstanding securities have entered into lock-up agreements with the underwriters pursuant to which they may not, with certain exceptions, for a period of 180 days from the date of this prospectus, offer, sell or otherwise transfer or dispose of any of our securities, without the prior written consent of the representatives of the underwriters. However, the representatives may permit our officers, directors and other security holders who are subject to the lock-up agreements to sell shares prior to the expiration of the lock-up agreements at any time in their sole discretion. See the section titled "Underwriters." Sales of these shares, or perceptions that they will be sold, could cause the trading price of our Class A Common Stock to decline. After the lock-up agreements expire, an additional shares of Class A Common Stock will be eligible for sale in the public market, of which shares are held by directors, executive officers and other affiliates and will be subject to volume limitations under Rule 144 under the Securities Act.

In addition, as of March 31, 2023, shares of Class A Common Stock that are subject to outstanding options and RSUs under our employee benefit plans will become eligible for sale in the public market after this offering, to the extent permitted by the provisions of various vesting schedules, the lock-up agreements (and the exceptions thereto) and Rule 144 and Rule 701 under the Securities Act. If these additional shares of Class A Common Stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our Class A Common Stock could decline.

After this offering, the holders of shares of our outstanding Class A Common Stock, or approximately % of our total outstanding Class A Common Stock based on shares outstanding as of March 31, 2023, will be entitled to rights with respect to the registration of their shares under the Securities Act, subject to the lock-up agreements described above. See "Description of Capital Stock—Registration Rights." Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares held by affiliates, as defined in Rule 144 under the Securities Act. Any sales of securities by these stockholders could adversely affect the trading price of our Class A Common Stock.

We have broad discretion in how we use the net proceeds of this offering and may not use these proceeds effectively, which could affect our results of operations and cause our stock price to decline.

We will have considerable discretion in the application of the net proceeds of this offering, including for any of the purposes described in the section of this prospectus titled "Use of Proceeds," and you will not have the opportunity as part of your investment decision to assess whether the net proceeds are being used appropriately. As a result, investors will be relying upon management's judgment with only limited information about our specific intentions for the use of the balance of the net proceeds of this offering. We may use the net proceeds for purposes that do not yield a significant return or any return at all for our stockholders. In addition, pending their use, we may invest the net proceeds from this offering in a manner that does not produce income or that loses value.

Our principal stockholders and management own a significant percentage of our Class A Common Stock and will be able to control matters subject to stockholder approval.

Based on shares of our Class A Common Stock outstanding as of , 2023, 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 completion of this offering, that same group will hold approximately % of our outstanding voting stock (assuming no exercise of the underwriters' over-allotment option, no exercise of our outstanding options or settlement of outstanding RSUs and no purchases of shares of Class A Common Stock in this offering by anyone of this group). The interests of these stockholders may not be the same as or may even conflict with your interests. For example, these stockholders could delay or prevent a change of control of our company, even if such a change of control would benefit our other stockholders, which could deprive our stockholders of an opportunity to receive a premium for their Class A Common Stock as part of a sale of our company or our assets and might affect the prevailing market price of our Class A Common Stock. The significant concentration of stock ownership may adversely affect the trading price of our Class A Common Stock due to investors' perception that conflicts of interest may exist or arise.

We are an "emerging growth company" and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our Class A Common Stock less attractive to investors.

We are an "emerging growth company" as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including (i) not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, (ii) reduced disclosure obligations regarding executive compensation in this prospectus and our periodic reports and proxy statements and (iii) exemptions from the requirements of holding nonbinding advisory stockholder votes on executive compensation and stockholder approval of any golden parachute payments not approved previously. In addition, as an emerging growth company, we are only required to provide two years of audited financial statements and two years of selected financial data in this prospectus.

We could be an emerging growth company for up to five years following the completion of this offering, although circumstances could cause us to lose that status earlier, including if we are deemed to be a "large accelerated filer," which occurs when the market value of our shares that is held by non-affiliates equals or exceeds $700.0 million as of the prior June 30, or if we have total annual gross revenue of $1.24 billion or more during any fiscal year before that time, in which cases we would no longer be an emerging growth company as of the December 31 of such year, or if we issue more than $1.0 billion in non-convertible debt during any three-year period before that time, in which case we would no longer be an emerging growth company immediately.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to take advantage of the benefits of this extended transition period. Our financial statements may therefore not be comparable to those of companies that comply with such new or revised accounting standards. Until the date that we are no longer an "emerging growth company" or affirmatively and irrevocably opt out of the exemption provided by Section 7(a)(2)(B) of the Securities Act, upon issuance of a new or revised accounting standard that applies to our financial statements and that has a different effective date for public and private companies, we will disclose the date on which adoption is required for non-emerging growth companies and the date on which we will adopt the recently issued accounting standard.

Anti-takeover provisions in our charter documents and under Delaware law could prevent or delay an acquisition of us that may be beneficial to our stockholders, and may prevent attempts by our stockholders to replace or remove our current management.

Our restated certificate of incorporation and our restated bylaws that will be in effect upon completion of this offering contain provisions that could delay or prevent a change in control of our company. These provisions could also make it difficult for stockholders to elect directors who are not nominated by current members of our board of directors or take other corporate actions, including effecting changes in our management. These provisions:

- establish a classified board of directors so that not all members of our board are elected at one time;
- permit only the board of directors to establish the number of directors and fill vacancies on the board;
- provide that directors may only be removed "for cause" and only with the approval of two-thirds of our stockholders;
- require super-majority voting to amend some provisions in our restated certificate of incorporation and restated bylaws;
- authorize the issuance of "blank check" preferred stock that our board could use to implement a stockholder rights plan;
- eliminate the ability of our stockholders to call special meetings of stockholders;
- prohibit stockholder action by written consent, which requires all stockholder actions to be taken at a meeting of our stockholders;
- prohibit cumulative voting; and
- establish advance notice requirements for nominations for election to our board or for proposing matters that can be acted upon by stockholders at annual stockholder meetings.

In addition, Section 203 of the Delaware General Corporation Law (DGCL) may discourage, delay or prevent a change in control of our company. Section 203 imposes certain restrictions on mergers, business combinations and other transactions between us and holders of 15% or more of our Class A Common Stock.

The exclusive forum provisions in our organizational documents may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, or employees, or the underwriters of any offering giving rise to such claim, which may discourage lawsuits with respect to such claims.

Our restated certificate of incorporation that will be in effect upon completion of this offering, to the fullest extent permitted by law, will provide that the Court of Chancery of the State of Delaware is the exclusive forum for: any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising pursuant to the DGCL, our restated certificate of incorporation, or our restated bylaws; or any action asserting a claim that is governed by the internal affairs doctrine. This exclusive forum provision does not apply to suits brought to enforce a duty or liability created by the Exchange Act.

This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, or other employees, or the underwriters of any offering giving rise to such claims, which may discourage lawsuits with respect to such claims. Alternatively, if a court were to find the choice of forum provisions contained in our restated 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 harm our business, financial condition, results of operations and prospects.

Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all claims brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. Our restated bylaws will provide that the federal district courts of the United States of America will, to the fullest extent permitted by law, be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, or the Federal Forum Provision, including for all causes of action asserted against any defendant named in such complaint. For the avoidance of doubt, this provision is intended to benefit and may be enforced by us, our officers and directors, the underwriters to any offering giving rise to such complaint, and any other professional entity whose profession gives authority to a statement made by that person or entity and who has prepared or certified any part of the documents underlying the offering. Our decision to adopt a Federal Forum Provision followed a decision by the Supreme Court of the State of Delaware holding that such provisions are facially valid under Delaware law. While federal or other state courts may not follow the holding of the Delaware Supreme Court or may determine that the Federal Forum Provision should be enforced in a particular case, application of the Federal Forum Provision means that suits brought by our stockholders to enforce any duty or liability created by the Securities Act must be brought in federal court and cannot be brought in state court, and our stockholders cannot waive compliance with the federal securities laws and the rules and regulations thereunder. Section 27 of the Exchange Act creates exclusive federal jurisdiction over all claims brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. In addition, neither the exclusive forum provision nor the Federal Forum Provision applies to suits brought to enforce any duty or liability created by the Exchange Act. Accordingly, actions by our stockholders to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder must be brought in federal court, and our stockholders cannot waive compliance with the federal securities laws and the rules and regulations thereunder.

Any person or entity purchasing or otherwise acquiring or holding any interest in any of our securities shall be deemed to have notice of and consented to our exclusive forum provisions in our restated bylaws, including the Federal Forum Provision. These provisions may limit a stockholders' ability to bring a claim, and may result in increased costs for a stockholder to bring such a claim, in a judicial forum of their choosing for disputes with us or our directors, officers, other employees or agents, which may discourage lawsuits against us and our directors, officers, other employees or agents.

Our board of directors will be authorized to issue and designate shares of our preferred stock 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 preferred stock, subject to limitations prescribed by applicable law, rules and regulations and the provisions of our amended and restated certificate of incorporation, and to establish from time to time the number of shares of preferred stock 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 Class A Common Stock, which may reduce our Class A Common Stock's value.

Because we do not anticipate paying any dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.

We have never declared nor paid dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development, operation and expansion of our business and we do not anticipate declaring or paying any dividends in the foreseeable future. As a result, capital appreciation of our Class A Common Stock, which may never occur, will be your sole source of gain on your investment for the foreseeable future.

General Risk Factors

Unstable economic and market conditions may have serious adverse consequences on our business, financial condition and stock price.

Global economic and business activities continue to face widespread uncertainties, and global credit and financial markets have experienced extreme volatility and disruptions in the past several years, including severely diminished liquidity and credit availability, rising inflation and monetary supply shifts, rising interest rates, labor shortages, declines in consumer confidence, declines in economic growth, increases in unemployment rates, recession risks, and uncertainty about economic and geopolitical stability (for example, related to the ongoing Russia-Ukraine conflict). The extent of the impact of these conditions on our operational and financial performance, including our ability to execute our business strategies and initiatives in the expected timeframe, as well as that of third parties upon whom we rely, will depend on future developments which are uncertain and cannot be predicted. There can be no assurance that further deterioration in economic or market conditions will not occur, or how long these challenges will persist. If the current equity and credit markets further deteriorate, or do not improve, it may make any necessary debt or equity financing more difficult, more costly, and more dilutive. Furthermore, our stock price may decline due in part to the volatility of the stock market and the general economic downturn.

If securities or industry analysts do not publish research or reports about our business, or if they publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our Class A Common Stock will be influenced in part by the research and reports that industry or securities analysts publish about us or our business. We do not have any control over the industry or securities analysts, or the content and opinions included in their reports and may never obtain research coverage by securities and industry analysts. If no or few securities or industry analysts commence coverage of us, or if analysts cease coverage of us, we could lost visibility in the financial markets, and the trading price for our Class A Common Stock could be impacted negatively. If any of the analysts who cover us publish inaccurate or unfavorable research or opinions regarding us, our business model, our intellectual property or our stock performance, or if our preclinical studies and clinical trials and operating results fail to meet the expectations of analysts, our stock price would likely decline.

We will incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives and corporate governance practices.

After the completion of this offering, as a public company, and particularly after we are no longer an emerging growth company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. The Securities Act, the Exchange Act, Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the Nasdaq Global Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, we expect these rules and regulations to substantially increase our legal and financial compliance costs and to make some activities more time consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain sufficient coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers. The increased costs may require us to reduce costs in other areas of our business. Moreover, these rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Failure to establish and maintain effective internal control over financial reporting could adversely affect our business and if investors lose confidence in the accuracy and completeness of our financial reports, the market price of our Class A Common Stock could be negatively affected.

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 internal control over financial reporting. Although we will be required to disclose changes made in our internal control over financial reporting on a quarterly basis, we will not be required to make our first annual assessment of our internal control over financial reporting 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 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 would need to issue a report that is adverse in the event that there are material weaknesses in our internal control over financial reporting.

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 controls can divert our management's attention from other matters that are important to the operation of our business. Additionally, in connection with the preparation of our financial statements for the year ended December 31, 2021, material weaknesses were identified in the design and operating effectiveness of our internal control over financial reporting. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis. If we are unable to remediate these material weaknesses, or we identify more material weaknesses that we are not able to remediate in time to meet the applicable deadline imposed upon us for compliance with the disclosure and attestation requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner or assert that our internal control over financial reporting is effective, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our Class A 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.

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 must design our disclosure controls and procedures to reasonably assure 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. 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. For example, our directors or executive officers could inadvertently fail to disclose a new relationship or arrangement causing us to fail to make any related party transaction disclosures. 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. In addition, we do not have a formal risk management program for identifying and addressing risks to our business in other areas.

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

The market price of our Class A Common Stock is likely to be volatile. The stock market in general, and Nasdaq and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of companies. In the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation (including the cost to defend against, and any potential adverse outcome resulting from any such proceeding) can be expensive, time-consuming, damage our reputation and divert our management's attention from other business concerns, which could seriously harm our business.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements that involve substantial risks and uncertainties. The forward-looking statements are contained principally in the sections titled "Prospectus Summary," "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations," "Business" and elsewhere in this prospectus. All statements other than statements of historical facts contained in this prospectus, including statements regarding our future results of operations and financial position, business strategy, product candidates, planned preclinical studies and clinical trials, results of preclinical studies and clinical trials, research and development costs, regulatory approvals, timing and likelihood of success, as well as plans and objectives of management for future operations, are forward-looking statements. These statements speak only as of the date of this prospectus and involve known and unknown risks, uncertainties and other important factors that are in some cases beyond our control and may cause our actual results, performance or achievements to be materially different from those expressed or implied by such forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as "anticipate," "may," "will," "should," "would," "expect," "plan," "anticipate," "could," "intend," "target," "project," "believe," "estimate," "predict," "potential," or "continue" or the negative of these terms or other similar expressions. Forward-looking statements contained in this prospectus include, but are not limited to, statements about:

- our plans relating to the development of izokibep, lonigutamab, XLRN-517 or any other product candidates we may develop, including additional indications that we may pursue;
- the characteristics, safety, tolerability and efficacy of izokibep, lonigutamab, XLRN-517 or any other product candidates we may develop;
- the timing, progress and results of our preclinical studies and clinical trials, including statements regarding the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available and our development plans;
- the timing and costs involved in obtaining and maintaining regulatory approval of izokibep, lonigutamab, XLRN-517 or any other product candidates we may develop, and the timing or likelihood of regulatory filings and approvals, including our expectation to seek special designations for certain of our product candidates for various diseases;
- our plans relating to commercializing izokibep, lonigutamab, XLRN-517 or any other product candidates we may develop, if approved, including the geographic areas of focus and our ability to grow a sales force;
- our estimates of the number of patients who suffer from the diseases we target, and the corresponding size of the market opportunities for izokibep, lonigutamab, XLRN-517 or any other product candidates we may develop in each of the diseases we target;
- our ability to successfully procure the manufacture and supply of izokibep, lonigutamab, XLRN-517 or any other product candidates we may develop for clinical trials and for commercial use, if approved;
- the rate and degree of market acceptance of izokibep, lonigutamab, XLRN-517 or any other product candidates we may develop, as well as the pricing and reimbursement of izokibep, lonigutamab, XLRN-517 or any other product candidates we may develop, if approved;
- our continued reliance on third parties to conduct clinical trials of izokibep, lonigutamab, XLRN-517 or any other product candidates we may develop, and for the manufacture and supply of our product candidates;
- the scope of protection we are able to establish and maintain for intellectual property rights, including izokibep, lonigutamab, XLRN-517 or any other product candidates we may develop;
- the success of competing therapies that are, or may become, available and other developments relating to our competitors and our industry;

- existing regulations and regulatory developments in the United States and other jurisdictions;
- the implementation of our business model and strategic plans for our business and operations;
- our ability to retain the continued service of our key professionals and to identify, hire, and retain additional qualified professionals;
- our ability to acquire additional product candidates and advance them into clinical development;
- our expectations regarding our financial performance, expenses, revenue opportunities, capital requirements and needs for additional financing;
- our ability to remediate the existing material weaknesses in our internal control over financial reporting;
- our expectations regarding the impact of the COVID-19 pandemic, geopolitical conflicts and economic uncertainty, including rising interest rates and inflation on our business and operations, including clinical trials, CMOs, collaborators, CROs and employees;
- our expectations regarding the period during which we will qualify as an emerging growth company under the JOBS Act; and
- our use of the net proceeds from this offering and the sufficiency of our existing cash to fund our future operating expenses and capital expenditure requirements.

We have based these forward-looking statements largely on our current expectations and projections about our business, the industry in which we operate and financial trends that we believe may affect our business, financial condition, results of operations and prospects and these forward-looking statements are not guarantees of future performance or development. These forward-looking statements speak only as of the date of this prospectus and are subject to a number of risks, uncertainties and assumptions described in the section titled “Risk Factors” and elsewhere in this prospectus. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein after we distribute this prospectus, whether as a result of any new information, future events or otherwise.

In addition, “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 while 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 an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain, and you are cautioned not to unduly rely upon them.

MARKET, INDUSTRY AND OTHER DATA

We obtained the industry, market and competitive position data used throughout this prospectus from our own internal estimates and research, as well as from market research, industry and general publications and surveys, governmental agencies, research, surveys and studies conducted by third parties and publicly available information. These sources include:

1. GlobalData (2019) Axial Spondyloarthritis: Global Drug Forecast and Market Analysis to 2028, October 2019, GDHC179PIDR; and
2. Skysis, a member of Fishawack Health. References in this prospectus to market research by Skysis were commissioned by us.

In presenting this information, we have made certain assumptions that we believe to be reasonable based on such data and other similar sources and on our knowledge of, and our experience to date in, the markets in which we operate. Internal estimates are derived from publicly available information released by industry analysts and third-party sources, our internal research and our industry experience, and are based on assumptions made by us based on such data and our knowledge of our industry and market, which we believe to be reasonable. In some cases, we do not expressly refer to the sources from which this data is derived. In that regard, when we refer to one or more sources of this type of data in any paragraph, you should assume that other data of this type appearing in the same paragraph is derived from the same sources, unless otherwise expressly stated or the context otherwise requires. In addition, while we believe the industry, market and competitive position data included in this prospectus is reliable and based on reasonable assumptions, such data involve risks and uncertainties and are subject to change based on various factors, including those discussed in the sections titled “Risk Factors” and “Special Note Regarding Forward-Looking Statements.” These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties or by us.

USE OF PROCEEDS

We estimate that we will receive net proceeds from this offering of approximately $ million (or approximately $ million if the underwriters' option to purchase additional shares of our Class A Common Stock is exercised in full) based on the assumed initial public offering price of $ per share, which is the midpoint of the estimated 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.

Each $1.00 increase or decrease in the assumed initial public offering price of $ per share, which is the midpoint of the estimated price range set forth on the cover page of this prospectus, would increase (decrease) the 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. Similarly, each increase (decrease) of 1,000,000 shares in the number of shares of Class A Common Stock offered by us would increase (decrease) the net proceeds to us from this offering by approximately $ million, assuming the assumed initial public offering price of $ per share remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The principal purposes of this offering are to obtain additional capital to support our operations, establish a public market for our Class A Common Stock and facilitate our future access to the public capital markets.

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

- to advance the clinical development of izokibep through ;
- to advance the clinical development of lonigutamab through ;
- to fund our other development efforts, including XLRN-517; and
- the remainder for general corporate purposes, including working capital, operating expenses and other capital expenditures.

We may also use a portion of the net proceeds and our existing cash to in-license, acquire, or invest in complementary businesses, technology platforms, products or assets, although we have no current agreements, commitments or understandings to do so.

Based on our current operating plan, we estimate that our existing cash as of the date of this prospectus, together with the estimated net proceeds from this offering, will be sufficient to fund our projected operating expenses and capital expenditure requirements through at least the next 12 months. Our expected use of proceeds from this offering described above represents our current intentions based on our present plans and business condition. As of the date of this prospectus, we cannot predict with certainty all of the particular uses for the proceeds to be received upon the closing of this offering or the actual amounts that we will spend on the uses set forth above.

The amounts and timing of our actual expenditures will depend on numerous factors, including the time and cost necessary to conduct our ongoing and planned preclinical studies and clinical trials, the results of our preclinical studies and clinical trials and other factors described in the section titled "Risk Factors" in this prospectus, as well as the amount of cash used in our operations and any unforeseen cash needs. Therefore, our actual expenditures may differ materially from the estimates described above. We may find it necessary or advisable to use the net proceeds for other purposes. We will have broad discretion over how to use the net proceeds to us from this offering. We intend to invest the net proceeds to us from this offering that are not used as described above in short-term, investment-grade, interest-bearing instruments.

DIVIDEND POLICY

We do not anticipate declaring or paying, in the foreseeable future, any cash dividends on our capital stock. We intend to retain all available funds and future earnings, if any, to fund the development and expansion of our business. Any future determination regarding the declaration and payment of dividends, if any, will be at the discretion of our board of directors, subject to applicable laws, and will depend on then-existing conditions, including our financial condition, operating results, contractual restrictions, capital requirements, business prospects and other factors our board of directors may deem relevant. In addition, our ability to pay cash dividends on our capital stock in the future may be limited by the terms of any future debt or preferred securities we issue or any credit facilities we enter into.

CAPITALIZATION

The following table sets forth our cash and capitalization as of March 31, 2023:

- on an actual basis;
- on a pro forma basis, giving effect to (i) the automatic conversion of outstanding shares of our redeemable convertible preferred stock into an equivalent number of shares of our Class A Common Stock which will occur immediately prior to the closing of this offering, (ii) shares of our Class A Common Stock issuable upon vesting and settlement of RSUs immediately upon the completion of this offering, and (iii) the filing and effectiveness of our amended and restated certificate of incorporation that will be in effect immediately prior to the closing of this offering; and
- on a pro forma as adjusted basis to give further effect to our issuance and sale of shares of our Class A Common Stock in this offering at the assumed initial public offering price of $ per share, which is the midpoint of the estimated 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.

	As of March 31, 2023		
	Actual	Pro Forma	Pro Forma As Adjusted[1]
	(in thousands, except share and per share data)		
Cash	$	$	$
Series A redeemable convertible preferred stock, $0.00001 par value per share; shares authorized, shares issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted	$	$	$
Series B redeemable convertible preferred stock, $0.00001 par value per share; shares authorized, shares issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted			
Series C redeemable convertible preferred stock, $0.00001 par value per share; shares authorized, shares issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted			
Stockholders' equity (deficit):			
Preferred stock, $0.00001 par value per share; no shares authorized, issued or outstanding, actual; shares authorized, and no shares issued or outstanding, pro forma and pro forma as adjusted			
Class A Common Stock, $0.00001 par value per share; shares authorized, shares issued and outstanding, actual; shares authorized, pro forma and pro forma as adjusted, shares issued and outstanding, pro forma, and shares issued and outstanding, pro forma as adjusted			
Class B Common Stock, $0.00001 par value per share; shares authorized, no shares issued and outstanding, actual; shares authorized, pro forma and pro forma as adjusted and no shares issued and outstanding, pro forma and pro forma as adjusted			
Additional paid-in capital			
Accumulated deficit			
Total stockholders' equity (deficit)			
Total capitalization	$	$	$

(1) The pro forma as adjusted information above is illustrative only, and our capitalization following the closing of this offering will be adjusted based on the actual initial public offering price and other terms of this offering determined at pricing. Each $1.00 increase (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 (decrease) each of our pro forma as adjusted cash, additional paid-in capital, total stockholders' equity (deficit) and total capitalization 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. Similarly, each increase (decrease) of 1,000,000 shares in the number of shares Class A Common Stock offered by us would increase (decrease) each of our pro forma as adjusted cash, additional paid-in capital, total stockholders' equity (deficit) and total capitalization by approximately $ million, assuming the assumed initial public offering price of $ per share remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

You should read this table together with the sections titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Description of Capital Stock," and our financial statements and the related notes included elsewhere in this prospectus.

The number of shares of our Class A Common Stock and Class B Common Stock to be outstanding after this offering is based on shares of Class A Common Stock outstanding as of March 31, 2023 (including shares of unvested restricted stock subject to a repurchase option by us, and giving effect to (i) the automatic conversion of shares of our redeemable convertible preferred stock into an equivalent number of shares of our Class A Common Stock, which will occur immediately prior to the closing of this offering, and (ii) the vesting of shares of our Class A Common Stock issuable upon vesting and settlement of RSUs upon the completion of this offering) and no shares of Class B Common Stock outstanding.

The number of shares of Class A Common Stock and Class B Common Stock to be outstanding after this offering excludes:

- shares of our Class A Common Stock issuable upon the exercise of outstanding stock options as of March 31, 2023 under our 2020 Plan, with a weighted-average exercise price of $ per share;
- shares of our Class A Common Stock issuable upon the exercise of outstanding stock options granted subsequent to March 31, 2023 under our 2020 Plan, with a weighted-average exercise price of $ per share;
- shares of our Class A Common Stock issuable upon the exercise of outstanding stock options assumed in connection with the Acquisition, with a weighted-average exercise price of $ per share;
- shares of our Class A Common Stock issuable upon vesting and settlement of RSUs outstanding as of March 31, 2023, net of RSUs, which will vest upon the completion of this offering;
- shares of our Class A Common Stock reserved for future issuance under our 2023 Plan, which will become effective once the registration statement of which this prospectus forms a part is declared effective, including new shares plus the number of shares (not to exceed shares) that (i) remain available for grant of future awards under the 2020 Plan and will cease to be available for issuance under the 2020 Plan at the time our 2023 Plan becomes effective in connection with this offering, and (ii) are underlying outstanding stock awards granted under our 2020 Plan, that expire or are repurchased, forfeited, cancelled or withheld, as well as any future automatic annual increases in the number of shares of Class A Common Stock reserved for issuance under our 2023 Plan, as more fully described in the section titled "Executive Compensation—Equity Benefit Plans;" and

- shares of our Class A Common Stock reserved for issuance under our ESPP, which will become effective once the registration statement of which this prospectus forms a part is declared effective, as well as any future automatic annual increases in the number of shares of Class A Common Stock reserved for future issuance under our ESPP, as more fully described in the section titled "Executive Compensation—Equity Benefit Plans."

DILUTION

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

As of March 31, 2023, our historical net tangible book value (deficit) was $ million, or $ per share of Class A Common Stock based on the shares of our Class A Common Stock (including shares subject to repurchase as of such date) and no shares of our Class B Common Stock outstanding as of such date. Our historical net tangible book value (deficit) per share represents the amount of our total tangible assets less our total liabilities, divided by the number of shares of our Class A Common Stock outstanding as of March 31, 2023 (including shares of Class A Common Stock subject to repurchase as of such date).

Our pro forma net tangible book value as of March 31, 2023 was $ million, or $ per share of Class A Common Stock. Pro forma net tangible book value per share represents the amount of our total tangible assets less our total liabilities after giving effect to (i) the automatic conversion of outstanding shares of our redeemable convertible preferred stock into an equivalent number of shares of our Class A Common Stock immediately prior to the closing of this offering, and the related reclassification of the carrying value of our redeemable convertible preferred stock to permanent equity, (ii) the issuance of shares of our Class A Common Stock upon the vesting and settlement of RSUs upon the completion of this offering and (iii) the filing and effectiveness of our amended and restated certificate of incorporation that will be in effect immediately prior to the closing of this offering. Pro forma net tangible book value per share represents pro forma net tangible book value divided by the total number of our Class A Common Stock outstanding as of March 31, 2023 (including shares of Class A Common Stock subject to repurchase as of such date), after giving effect to the pro forma adjustments described above.

After giving effect to our issuance and sale of shares of our Class A Common Stock in this offering at the assumed initial public offering price of $ per share, the midpoint of the estimated 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 March 31, 2023 would have been $ million, or $ per share of our Class A Common Stock. This amount represents an immediate increase in pro forma as adjusted net tangible book value of $ per share to our existing stockholders and an immediate dilution in pro forma as adjusted net tangible book value of $ per share to new investors purchasing Class A Common Stock in this offering. We determine dilution by subtracting the pro forma as adjusted net tangible book value per share after this offering from the 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 March 31, 2023	$	
Increase per share attributable to the automatic conversion of redeemable convertible preferred stock into Class A Common Stock upon the closing of this offering		
Pro forma net tangible book value per share as of March 31, 2023		
Increase in pro forma as adjusted net tangible book value per share attributable to new investors purchasing Class A Common Stock in this offering		
Pro forma as adjusted net tangible book value per share immediately after this offering		
Dilution per share to new investors purchasing Class A Common Stock in this offering		$

The dilution information discussed above is illustrative only and may change based on the actual initial public offering price and other terms of this offering. Each $1.00 increase or decrease in the assumed initial public offering price of $ per share, which is the midpoint of the estimated price range set forth on the cover page of this prospectus, would increase (decrease) our pro forma as adjusted net tangible book value per share after this offering by $ per share and increase (decrease) the dilution to new investors purchasing shares of Class A Common Stock in this offering by $ per share, in each case assuming the number of shares of Class A 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 (decrease) of 1,000,000 shares in the number of shares of Class A Common Stock offered by us would increase (decrease) our pro forma as adjusted net tangible book value by approximately $ per share and decrease (increase) the dilution to investors purchasing shares in this offering by approximately $ per share, in each case assuming the assumed initial public offering price of $ per share remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

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

The following table summarizes on the pro forma as adjusted basis as of March 31, 2023, the total number of shares of Class A Common Stock purchased from us, the total consideration paid or to be paid, and the weighted-average price per share paid or to be paid by existing stockholders and by new investors in this offering at an assumed initial public offering price of $ per share, which is the midpoint of the estimated price range set forth on the cover of this prospectus, before deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. As the table shows, new investors purchasing Class A Common Stock in this offering will pay an average price per share substantially higher than our existing stockholders paid.

	Total Shares		Total Consideration		Weighted-Average Price Per Share
	Number	Percentage	Amount	Percentage	
Existing stockholders		%	$	%	$
New investors					$
Total		100.0%	$	100.0%	

The table above assumes no exercise of the underwriters' option to purchase additional shares in this offering. If the underwriters' option to purchase additional shares is exercised in full, the number of shares of our Class A Common Stock held by existing stockholders would be reduced to % of the total number of shares of our Class A Common Stock outstanding after this offering, and the number of shares of Class A Common Stock held by new investors purchasing Class A Common Stock in this offering would be increased to % of the total number of shares of our Class A Common Stock outstanding after this offering.

The number of shares of our Class A Common Stock and Class B Common Stock to be outstanding after this offering is based on shares of Class A Common Stock outstanding as of March 31, 2023 (including shares of unvested restricted stock subject to a repurchase option by us, and giving effect to (i) the automatic conversion of shares of our redeemable convertible preferred stock into an equivalent number of shares of our Class A Common Stock, which will occur immediately prior to the closing of this offering, and (ii) the vesting of shares of our Class A Common Stock issuable upon vesting and settlement of RSUs upon the completion of this offering) and no shares of Class B Common Stock outstanding.

The number of shares of Class A Common Stock and Class B Common Stock to be outstanding after this offering in the table and discussion above excludes:

- shares of our Class A Common Stock issuable upon the exercise of outstanding stock options as of March 31, 2023 under our 2020 Plan, with a weighted-average exercise price of $ per share;
- shares of our Class A Common Stock issuable upon the exercise of outstanding stock options granted subsequent to March 31, 2023 under our 2020 Plan, with a weighted-average exercise price of $ per share;
- shares of our Class A Common Stock issuable upon the exercise of outstanding stock options assumed in connection with the Acquisition, with a weighted-average exercise price of $ per share;
- shares of our Class A Common Stock issuable upon vesting and settlement of RSUs outstanding as of March 31, 2023 net of RSUs, which will vest upon completion of this offering;
- shares of our Class A Common Stock reserved for future issuance under our 2023 Plan, which will become effective once the registration statement of which this prospectus forms a part is declared effective, including new shares plus the number of shares (not to exceed shares) that (i) remain available for grant of future awards under the 2020 Plan and will cease to be available for issuance under the 2020 Plan at the time our 2023 Plan becomes effective in connection with this offering, and (ii) are underlying outstanding stock awards granted under our 2020 Plan, that expire or are repurchased, forfeited, cancelled or withheld, as well as any future automatic annual increases in the number of shares of Class A Common Stock reserved for issuance under our 2023 Plan, as more fully described in the section titled "Executive Compensation—Equity Benefit Plans;" and
- shares of our Class A Common Stock reserved for issuance under our ESPP, which will become effective once the registration statement of which this prospectus forms a part is declared effective, as well as any future automatic annual increases in the number of shares Class A Common Stock reserved for future issuance under our ESPP, as more fully described in the section titled "Executive Compensation—Equity Benefit Plans."

To the extent that any outstanding options are exercised or new options or RSUs are issued under our stock-based compensation plans, or we issue additional shares of our Class A Common Stock in the future, there will be further dilution to new investors participating in this offering.

UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL INFORMATION

The following unaudited pro forma condensed combined statements of operations present the combination of the historical financial statements of ACELYRIN, INC. (the Company or ACELYRIN) and ValenzaBio, Inc. (ValenzaBio) adjusted to give effect to the transactions contemplated by the Merger and Reorganization Agreement (the ValenzaBio Merger Agreement), dated December 20, 2022, by and among ACELYRIN, ValenzaBio, WH1, Inc. (Merger Sub I), WH2, LLC (Merger Sub II) and Seller Representatives LLC (Seller LLC). The ValenzaBio Merger Agreement contemplates, among other things, the merger of Merger Sub I with and into ValenzaBio, with ValenzaBio as the surviving entity and continuing as a direct, wholly owned subsidiary of the Company (the First Merger), and promptly thereafter, the merger of ValenzaBio with and into Merger Sub II, with Merger Sub II as the surviving entity and continuing as a direct, wholly owned subsidiary of the Company (the Second Merger) (collectively, the Acquisition). The Acquisition closed on January 4, 2023 (the Closing Date) and is anticipated to qualify as a tax-free reorganization for U.S. federal income tax purposes. On the Closing Date, the Company (i) issued 37,242,709 shares of its Class A Common Stock and paid $16,050 in cash to one non-accredited investor in exchange for 100% of the outstanding common stock of ValenzaBio and (ii) assumed options of ValenzaBio optionholders who entered into consulting agreements with the Company, which are now exercisable for an aggregate of 2,464,653 shares of the Company's Class A Common Stock. Outstanding shares and options were exchanged at an exchange ratio of 1.582963-for-one.

The unaudited pro forma condensed combined statements of operations for the year ended December 31, 2022 and for the three months ended March 31, 2023 give effect to the Acquisition assuming that it closed on January 1, 2022 and are based upon and derived from:

- ACELYRIN's statement of operations and comprehensive loss information for the year ended December 31, 2022, included elsewhere in this prospectus.
- ValenzaBio's statement of operations and comprehensive loss information for the year ended December 31, 2022, included elsewhere in this prospectus.
- ACELYRIN's statement of operations and comprehensive loss for three months ended March 31, 2023, included elsewhere in this prospectus.
- ValenzaBio's statement of operations and comprehensive loss for the period from January 1, 2023 to January 4, 2023, which was prepared by ValenzaBio's management and is not included in this prospectus.

The pro forma adjustments are preliminary and are based upon available information and certain assumptions, as described in the accompanying notes to the unaudited pro forma condensed combined statements of operations, which the Company believes are reasonable under the circumstances. Actual results and valuations may differ materially from the assumptions within the unaudited pro forma condensed combined statements of operations. An unaudited pro forma condensed combined balance sheet has not been presented as the Acquisition is reflected in the historical balance sheet of the Company as of March 31, 2023 that is included in the Company's unaudited condensed consolidated financial statements as of and for the three months ended March 31, 2023, which are included elsewhere in this prospectus.

The unaudited pro forma condensed combined statements of operations have been prepared in accordance with the regulations of the Securities and Exchange Commission and are not necessarily indicative of the financial position or results of operations to be expected in future periods or the results that actually would have been realized had the Company and ValenzaBio been a combined company during the specified periods. The unaudited pro forma condensed combined statements of operations do not give effect to the potential impact of current financial conditions, regulatory matters, operating efficiencies or other savings or expenses that may be associated with the Acquisition. The unaudited pro forma condensed combined statements of operations also do not include any future integration costs.

The assumptions and estimates underlying the adjustments to the unaudited pro forma condensed combined statements of operations are described in the accompanying notes, which should be read together with the unaudited pro forma condensed combined statements of operations as well as the historical financial statements and accompanying notes of the Company and ValenzaBio included elsewhere in this prospectus.

Unaudited Pro Forma Condensed Combined Statement of Operations
For the Three Months Ended March 31, 2023
(in thousands, except share and per share data)

	ACELYRIN, INC.	ValenzaBio, Inc. 1/1/23 – 1/4/23	Transaction Adjustments	Notes	Pro Forma Condensed Combined
Operating expenses:					
Research and development	$	$	$		$
General and administrative					
Total operating expenses					
Loss from operations					
Other income (expense), net					
Net loss	$	$	$		$
Net loss per share attributable to common stockholders, basic and diluted	$				$
Weighted-average common shares outstanding, basic and diluted					

See the accompanying "Notes to Unaudited Pro Forma Condensed Combined Statements of Operations" beginning on page 95.

Unaudited Pro Forma Condensed Combined Statement of Operations
For the Year Ended December 31, 2022
(in thousands, except share and per share data)

	ACELYRIN, INC.	ValenzaBio, Inc.	Transaction Adjustments	Notes	Pro Forma Condensed Combined
Operating expenses:					
Research and development	$	$	$		$
General and administrative					
Total operating expenses					
Loss from operations					
Other income (expense), net					
Net loss	$	$	$		$
Net loss per share attributable to common stockholders, basic and diluted	$				$
Weighted-average common shares outstanding, basic and diluted					

See the accompanying "Notes to Unaudited Pro Forma Condensed Combined Statements of Operations" beginning on page 95.

NOTES TO UNAUDITED PRO FORMA CONDENSED COMBINED STATEMENTS OF OPERATIONS

1. Description of the ValenzaBio Acquisition

On December 20, 2022, the Company entered into the ValenzaBio Merger Agreement by and among the Company, ValenzaBio, Merger Sub I, Merger Sub II, and Seller LLC. The Acquisition closed on January 4, 2023 (the Closing Date), when as a result of consummation of a series of mergers between Merger Sub I, Merger Sub II and ValenzaBio, Merger Sub I was liquidated and Merger Sub II acquired all assets and liabilities of ValenzaBio, such that ValenzaBio became a wholly owned subsidiary of the Company.

ValenzaBio was a privately held company developing therapies for autoimmune and inflammatory diseases. The Acquisition added additional assets into the Company's portfolio, including lonigutamab and XLRN-517.

As consideration, the Company issued 37,242,709 shares of its Class A Common Stock to ValenzaBio stockholders, of which 10% is being held by Seller LLC for any post-acquisition costs and general indemnities for 12 months from the Closing Date, and paid $16,050 in cash to one non-accredited investor. The Company also assumed options of ValenzaBio optionholders who entered into consulting agreements with the Company, which are now exercisable for an aggregate of 2,464,653 shares of the Company's Class A Common Stock. The assumed options vest in full on the earliest of (i) March 31, 2023 or (ii) the termination of the optionholder's consulting agreement without cause. Each assumed option is exercisable until the earlier of (i) 12 months following the termination of the optionholder's continuous service with the Company, or (ii) the original expiration date of such assumed option. Outstanding shares and options were exchanged at an exchange ratio of 1.582963-for-one.

In connection with the Acquisition, all 17 ValenzaBio employees were terminated and 14 of these employees entered into consulting agreements with the Company through March 31, 2023.

The Company agreed to make severance payments to certain former ValenzaBio employees of approximately $5.1 million in the aggregate for a period of three to 18 months (depending on the position and tenure of such employees) from the Closing Date. In connection with the Acquisition, the Company negotiated an amendment, effective as of January 4, 2023, to the Pierre Fabre Medicament SAS (Pierre Fabre) license and commercialization agreement. In connection with the amendment, the Company paid an additional $10.0 million non-refundable license fee to Pierre Fabre.

2. Basis of Presentation

The unaudited pro forma condensed combined statements of operations have been prepared by the Company in accordance with Article 11 of Regulation S-X. The pro forma condensed combined financial information reflects transaction accounting adjustments management believes are necessary to present fairly the Company's pro forma results of operations following the closing of the Acquisition for the periods indicated.

The unaudited pro forma condensed combined statements of operations for the year ended December 31, 2022 and for the three months ended March 31, 2023 are based upon and derived from the historical financial information of the Company and ValenzaBio and are presented as if the Acquisition had occurred on January 1, 2022. The transaction accounting adjustments depict the accounting for the Acquisition as required by U.S. GAAP. The unaudited pro forma condensed combined financial information does not reflect any anticipated synergies or dis-synergies, operating efficiencies or cost savings that may result from the Acquisition and integration costs that may be incurred. The pro forma adjustments represent the Company's best estimates and are based upon currently available information and certain assumptions that the Company believes are reasonable under the circumstances.

3. Pro Forma Adjustments

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 in conjunction with our financial statements and the related notes and other financial information included elsewhere in this prospectus. This discussion and analysis and other parts of this prospectus contain forward-looking statements based upon our current plans and expectations that involve risks, uncertainties and assumptions, such as statements regarding our plans, objectives, expectations, intentions and beliefs. Our actual results and the timing of events could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth under the section titled "Risk Factors" and elsewhere in this prospectus. You should carefully read the section titled "Risk Factors" to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements. Please also see the section titled "Special Note Regarding Forward-Looking Statements."

Overview

ACELYRIN is a late-stage clinical biopharma company focused on identifying, acquiring, and accelerating the development and commercialization of transformative medicines. We are driven by our sense of urgency to bring life-changing therapies to patients globally, a core value that we refer to as "courageous caring." Our initial focus is on the treatment of diseases with pathology related to excess activation of the immune system, an area where our management and team bring industry-leading expertise. We acquired our portfolio of product candidates with the intent to develop and commercialize novel therapies that we believe provide the opportunity to offer clinically meaningful, differentiated benefits for patients by improving upon the efficacy and/or safety of existing therapeutics directed against established targets, such as currently marketed anti-IL-17A agents, or by targeting new modalities. In each case, our strategy is to identify candidates we believe are "diamonds in the rough," where, based on molecule characteristics, our collective experience and expertise, and the evolving scientific and medical understanding, we can establish a clinical development plan that tests our hypotheses as to what those novel benefits could mean for patients. Subsequently, we utilize the results we obtain in initial clinical trials and the learnings we obtain from emerging biology to expand the application of our candidates to other indications in which there are high unmet needs.

Our current portfolio consists of multiple clinical and preclinical stage candidates being investigated in trials and studies across several indications representing multi-billion-dollar opportunities in the aggregate. Our lead product candidate is izokibep, a small protein therapeutic designed to inhibit IL-17A with higher potency through exponentially higher binding affinity and the potential for greater tissue penetration compared to traditional monoclonal antibodies due to its markedly smaller size. In numerous clinical trials, izokibep has demonstrated clinically meaningful benefits and is currently in development for multiple immunological indications including HS, PsA, AxSpA and uveitis. As a result of our encouraging data in HS and PSA, we have prioritized development in these indications. For HS, in addition to the ongoing trial below, we plan to begin a second Phase 3 trial. For PSA, we accelerated into 2022 the initiation of a Phase 2b/3 trial evaluating a range of doses, including significantly higher doses than the Phase 2 trial based on our pharmacokinetics-pharmacodynamics (PK-PD) modeling that suggests increasing duration of treatment and higher doses could result in continued improvement of clinical outcomes. We are currently conducting a Phase 2b/3 trial of izokibep in HS; a Phase 2b/3 trial of izokibep in PsA; and a Phase 2b/3 trial of izokibep in uveitis. In addition to the ongoing trials in uveitis and HS, we plan to initiate confirmatory Phase 3 trials in both indications. Additionally, we plan to initiate two Phase 3 trials in AxSpA based on dosing data from the ongoing PsA Phase 2b/3 trial. In addition, we are advancing lonigutamab for the treatment of TED, and plan to evaluate it in other indications. We are also developing XLRN-517, a monoclonal antibody targeting c-KIT, for the treatment of chronic urticaria.

Since our inception in July 2020, we have devoted substantially all of our resources to organizing our company, hiring personnel, business planning, acquiring and developing our product candidates, performing research and development, enabling manufacturing activities in support of our product development efforts,

establishing and protecting our intellectual property portfolio, raising capital, and providing general and administrative support for these activities. We do not have any products approved for sale and have not generated any revenue from product sales. We expect to continue to incur significant and increasing expenses and substantial losses for the foreseeable future as we continue our development of and seek regulatory approvals for our product candidates and commercialize any approved products, seek to expand our product pipeline and invest in our organization. Our ability to achieve and sustain profitability will depend on our ability to successfully develop, obtain regulatory approval for and commercialize our product candidates. There can be no assurance that we will ever earn revenues or achieve profitability, or if achieved, that the revenues or profitability will be sustained on a continuing basis.

To date, we have primarily funded our operations with proceeds from sales of shares of our redeemable convertible preferred stock in private placements. Through December 31, 2021, we had received aggregate gross proceeds of $133.0 million from sales of shares of our redeemable convertible preferred stock. In addition, in February 2022 and in September 2022, we received aggregate gross proceeds of $125.0 million and $150.0 million from the sale of our Series B redeemable convertible preferred stock and Series C redeemable convertible preferred stock, respectively. We also have a commitment from our Series C investors to purchase an additional $150.0 million of shares of Series C redeemable convertible preferred stock on June 30, 2023 if this offering is not completed by such date, among other factors as discussed below.

In accordance with the Series C preferred stock purchase agreement, the second tranche of our Series C financing will be funded on June 30, 2023 if: (i) there has not occurred a closing of a deemed liquidation event, as defined in our certificate of incorporation; (ii) there has not occurred a closing of the first underwritten public offering of our Class A Common Stock under the Securities Act or an initial listing of our Class A Common Stock under the Securities Act via a direct listing; (iii) we have not filed for bankruptcy or otherwise become subject to involuntary bankruptcy or insolvency proceedings; (iv) Shao-Lee Lin, M.D., Ph.D. remains employed full-time as our Chief Executive Officer; (v) a majority of our board of directors including at least one independent director (as defined in our Amended and Restated Voting Agreement entered into in September 2022) has not resolved to (a) discontinue the development of izokibep or (b) remove the Phase 3 development of AxSpA from our long-range plan; and (vi) a majority of our board of directors, including at least one independent director has not determined that a material adverse change (as defined in the Series C preferred stock purchase agreement) has occurred since the initial closing of the first tranche of the Series C. The rights, preferences and privileges of the Series C stockholders are similar to those of the Series B stockholders, except that in the event of the liquidation, dissolution, or winding up, or a deemed liquidation event, they are entitled to their liquidation preference amount before any distribution to Series B stockholders.

The obligation of the Series C investors to purchase shares was concluded to be a tranche right liability and upon the first closing of the first tranche of the Series C financing in September 2022, we recorded a preferred stock tranche right liability of $10.8 million and a corresponding reduction to the carrying value of the Series C redeemable convertible preferred stock.

We have incurred significant losses and negative cash flows from operations since our inception. Our net loss for the year ended December 31, 2021 was $41.8 million. As of December 31, 2021, we had an accumulated deficit of $42.3 million. Substantially all of our net losses have resulted from costs incurred in connection with our research and development programs and, to a lesser extent, from general and administrative costs associated with our operations. Our net losses and operating losses may fluctuate from quarter to quarter and year to year depending primarily on the timing of acquisition of any new product candidates, the timing of our preclinical studies and clinical trials, our other research and development expenses, and the timing and amount of any milestone or royalty payments due under our existing or future license agreements. In addition, following the closing of this offering, we expect to incur additional costs associated with operating as a public company, including significant legal, audit, accounting, regulatory and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, director and officer liability insurance costs, investor

and public relations costs, and other expenses that we did not incur as a private company. We anticipate that our expenses will increase significantly in connection with our ongoing activities, particularly if and as we:

- continue to progress the development of our product candidates, including izokibep in multiple clinical trials in parallel, lonigutamab into later-stage clinical development and XLRN-517 into the clinic;
- explore additional indications for our existing product candidates;
- hire additional clinical, quality control and scientific personnel;
- obtain, maintain, expand and protect our intellectual property rights;
- make royalty, milestone, or other payments under current, and any future, license or collaboration agreement;
- seek to identify, acquire or in-license new technologies or product candidates;
- seek regulatory and marketing approvals for any of our product candidates that successfully complete clinical trials, if any;
- procure manufacturing and supply chain capacity for our product candidates, including commercial manufacturing readiness and scale-up;
- experience any delays, challenges, or other issues associated with the clinical development of our product candidates, including with respect to our regulatory strategies;
- add operational, legal, financial and management information systems and personnel to support our product development, clinical execution and planned future commercialization efforts, as well as to support our transition to a public company;
- establish a sales, marketing, and distribution infrastructure to commercialize any product candidates for which we obtain marketing approval; and
- operate as a public company.

Because of the numerous risks and uncertainties associated with therapeutic product development, we may never achieve or sustain profitability and, unless and until we are able to develop and commercialize our product candidates, we will need to continue to raise additional capital. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through public or private equity or debt financings, or potentially other capital sources, such as collaboration or licensing arrangements with third parties or other strategic transactions. There are no assurances that we will be successful in obtaining an adequate level of financing to support our business plans when needed on acceptable terms, or at all. 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 or could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing and equity 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 collaboration or licensing arrangements with third parties or other strategic transactions, we may have to relinquish rights to our intellectual property, 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 capital as and when needed, or on attractive terms, we may have to significantly delay, reduce, or discontinue the development and commercialization of our product candidates or scale back or terminate our pursuit of new in-licenses and acquisitions.

As of March 31, 2023, we had $ million in cash. Based on our current operating plan, we estimate that our existing cash as of the date of this prospectus, together with the estimated net proceeds from this offering, will be sufficient to fund our projected operating expenses and capital expenditure requirements through at least the next 12 months. We have based this estimate on our current assumptions, which may prove to be wrong, and we may exhaust our available capital resources sooner than we expect.

We currently have no sales, marketing or commercialization capabilities. However, we intend to build the necessary sales, marketing and commercialization capabilities and infrastructure over time as our product candidates advance through clinical development. We expect to spend a significant amount in development and marketing costs prior to obtaining regulatory and marketing approval of one or more of our product candidates. We expect that our expenses and capital requirements will increase substantially in the near- to mid-term as we continue our late-stage development efforts for izokibep and to advance lonigutamab and for our preclinical programs; and add clinical, scientific, sales and marketing, operational and financial personnel, including personnel to support our product development and potential future commercialization activity.

Macroeconomic Trends and the Impact of the COVID-19 Pandemic

We continue to actively monitor the impact of various macroeconomic trends, such as high rates of inflation, supply chain disruptions and geopolitical instability, and the COVID-19 pandemic on our business. To date, we have not experienced a material financial statement impact or business disruptions, including with our vendors or third parties, as a result of these negative macroeconomic trends or the COVID-19 pandemic. Our business has been, and may continue to be, impacted by the negative macroeconomic trends and the COVID-19 pandemic wherever we have clinical trial sites, CMO facilities or other business operations.

Economic conditions, such as rising inflation, higher interest rates, changes in regulatory laws and monetary exchange rates, and government fiscal policies, can also have a significant effect on operations. Moreover, negative macroeconomic conditions could adversely impact our ability to obtain financing in the future on terms acceptable to us, or at all. In addition, the geopolitical instability and related sanctions could continue to have significant ramifications on global financial markets, including volatility in the U.S. and global financial markets.

The COVID-19 pandemic has caused, and could continue to cause disruption in the operations of CMOs, CROs, and other third parties upon whom we rely. Our headquarters are located in California, our CMOs are located in the United States, Europe and China, and our CROs and clinical trial sites are located in multiple jurisdictions, including the United States and Europe. In reaction to the COVID-19 pandemic, we implemented and will continue to provide a flexible work-from-home policy allowing employees to work from home in jobs where that is reasonable. The effects of our work-from-home policies may negatively impact productivity, disrupt our business and delay our clinical programs and timelines. These and similar, and perhaps more severe, disruptions in our operations could negatively impact our business, financial condition, results of operations and prospects.

To date, the COVID-19 pandemic has not had a material adverse impact on our productivity or our business, and as of December 31, 2021, we have not identified any significant disruption or impairment of our assets due to the pandemic. However, as COVID-19 transitions from a pandemic to an endemic, we cannot predict the potential future impacts of COVID-19 on us and third parties with whom we conduct business. These impacts will depend on future developments that are highly uncertain and cannot be predicted at this time. Given these uncertainties, COVID-19 could impact our business operations and our ability to execute on our associated business strategies and initiatives, and adversely impact our results of operations and our financial condition in the future, and could disrupt the business of third parties with whom we do business. We will continue to closely monitor and evaluate the nature and extent of the impacts of COVID-19 on our business, financial condition, results of operations, and prospects.

ValenzaBio Acquisition

On December 20, 2022, we entered into the ValenzaBio Merger Agreement to acquire outstanding equity of ValenzaBio. The Acquisition closed on January 4, 2023. ValenzaBio was a privately held company developing therapies for autoimmune and inflammatory diseases. The acquisition of ValenzaBio added additional assets to our portfolio, including lonigutamab and XLRN-517. As consideration, at the closing, we (i) issued 37,242,709 shares of our Class A Common Stock to ValenzaBio stockholders and paid $16,050 in cash to one non-accredited investor, and (ii) assumed options of ValenzaBio optionholders who entered into consulting agreements with us, which are now exercisable for an aggregate of 2,464,653 shares of our Class A Common Stock. Outstanding

shares and options were exchanged at an exchange ratio of 1.582963-for-one. The assumed options vest in full on the earliest of (i) March 31, 2023 and (ii) the termination of the optionholder's consulting agreement without cause. Each assumed option is exercisable until the earlier of (i) 12 months following the termination of the optionholder's continuous service with us, or (ii) the original expiration date of such assumed option.

License and Collaboration Agreements

Below is a summary of the key terms for certain of our license and collaboration agreements. For a more detailed description of these agreements, see the section titled "Business—License and Collaboration Agreements."

Affibody Agreement

On August 9, 2021, we entered into a license agreement with Affibody AB (Affibody) (the Affibody Agreement) under which Affibody granted us exclusive, sublicensable licenses to develop, commercialize and manufacture products containing izokibep for all human therapeutic uses on a worldwide basis, subject to a pre-existing agreement with Inmagene Biopharmaceuticals (Inmagene) with respect to certain Asian countries.

We chair a global joint steering committee composed of our designees, as well as designees from Affibody and Inmagene. As chair of the global joint steering committee, we retain final decision-making authority for izokibep global development. In exercising this decision-making authority, we are obligated to use commercially reasonable efforts (i) to develop products containing izokibep worldwide, excluding certain defined territories, (ii) for the conduct and finalization of certain ongoing clinical trials, and (iii) to commercialize products containing izokibep for all human therapeutic uses worldwide, excluding certain defined territories, after obtaining the applicable marketing authorization. We are responsible for manufacturing both the clinical and commercial supply of licensed product globally.

In connection with the Affibody Agreement, we paid a non-refundable upfront license fee in the aggregate amount of $3.0 million in August 2021 and September 2021, and $22.0 million in October 2021. We are also obligated to pay Affibody (i) an aggregate of up to $280.0 million, $30.0 million of which would be due prior to the first approval in the United States, upon the achievement of various development, regulatory and commercialization milestones and (ii) high single-digit to low-teens royalties on net sales of licensed products in the territory where we have commercialization rights, subject to certain reductions. Royalties will be due on a licensed product-by-licensed product and country-by-country basis beginning after the first commercial sale of the licensed product, except in Mainland China, Hong Kong, Macau, Taiwan and South Korea, and lasting until the later of (a) the expiration of all valid patent claims or regulatory exclusivity covering the licensed product in that country and (b) ten years after such first commercial sale.

In the event the FDA grants us (or our affiliates or sublicensees) a priority review voucher for a licensed product, we will pay Affibody either: (a) if we sell or transfer such priority review voucher to a third-party, approximately one third of the proceeds received from the sale, net of taxes, or (b) if we use the priority review voucher for an indication or product outside the scope of the Affibody Agreement, approximately one third of the fair market value of the priority review voucher as determined in accordance with the Affibody Agreement.

Unless earlier terminated, the Affibody Agreement will continue on a licensed product-by-licensed product basis and country-by-country basis until there are no more royalty payments owed to Affibody on any licensed product thereunder. Either party may terminate the Affibody Agreement upon an uncured material breach by, or upon the bankruptcy, reorganization, liquidation or receivership proceedings of, the other party. In addition, each party may terminate the agreement upon 30 days' written notice in the event that certain clinical events create a serious and material risk of compromising patient safety. Either party may also terminate the agreement if the other party or any of its affiliates institutes a patent challenge against certain background patent rights for licensed products. The Affibody Agreement may also be terminated by us for convenience (i) upon 90 days' prior written notice to Affibody if the termination is before the first commercial sale of a licensed product, or (ii) upon 180 days' prior written notice if the termination is after the first commercial sale of a licensed product.

The acquisition of the exclusive license was accounted for as an in-process research and development asset acquisition and as the acquired technology did not have an alternative use, the total consideration of $25.0 million was recorded as research and development expense in the statement of operations and comprehensive loss for the year ended December 31, 2021. Milestone payments are contingent consideration and are accrued when contingent events occur and achievement of milestones is probable. Royalties will be recognized as cost of sales when products are sold and royalties are payable. No milestone or royalties were probable and estimable as of December 31, 2021.

Pierre Fabre Agreement

Upon the closing of the Acquisition, we became successors to ValenzaBio's rights under the March 25, 2021 license and commercialization agreement between ValenzaBio and Pierre Fabre, as amended. We received certain exclusive worldwide licenses with the right to sublicense to certain patents, know-how and other intellectual property to develop, manufacture, use and commercialize lonigutamab for non-oncology therapeutic indications. Our license from Pierre Fabre extends to any product containing lonigutamab (excluding any fragments or derivatives) as its sole active ingredient (each, a PF Licensed Product). The Pierre Fabre Agreement prohibits us from using the licensed intellectual property in any antibody drug conjugate, multi-specific antibodies or any other derivatives of lonigutamab.

In the event we decide to sublicense the rights to develop or commercialize a PF Licensed Product in any territory outside of the United States and Canada, Pierre Fabre retains the right of first negotiation to acquire such development and commercialization rights in one or more countries in such territory. Subject to the validation of certain clinical trial criteria by a joint steering committee, Pierre Fabre has the option to reclaim all exclusive rights to develop, commercialize and exploit the PF Licensed Product in such territories and to obtain an exclusive sublicensable license in such territories for any improvements and trademarks to such PF Licensed Product, and to exploit such PF Licensed Product for non-oncology therapeutic indications, subject to certain payment obligations. If Pierre Fabre exercises such option, and intends to sublicense such rights, then we will have the right of first negotiation to acquire such development and commercialization rights as to that territory, or Pierre Fabre has the right to require us to buy out its right to the option for a one-time payment of $31.0 million or we have the right to choose to buy out Pierre Fabre's option by making the one-time payment of $31.0 million within 30 days from Pierre Fabre's notice of exercise of such option. If Pierre Fabre does not exercise its option within the option period or if we buy out Pierre Fabre's right to the option, the option will expire or terminate, respectively. We are solely responsible for the development, regulatory approvals and commercialization of each PF Licensed Product except to the extent that Pierre Fabre reclaims rights to a PF Licensed Product in the option territory.

In connection with the original Pierre Fabre Agreement, ValenzaBio made an aggregate license payment of $7.5 million to Pierre Fabre, and issued Pierre Fabre 1,053,319 shares of ValenzaBio's Series A Preferred Stock. As consideration for the amendment to the original Pierre Fabre Agreement, we paid Pierre Fabre an aggregate license payment of $10.0 million. Furthermore, in connection with the closing the merger with ValenzaBio, Pierre Fabre's Series A Preferred Stock in ValenzaBio was converted into 1,667,326 shares of our Class A Common Stock. We are also obligated to (i) make payments of up to $99.5 million upon the achievement of various development and regulatory milestones, (ii) make milestone payments of up to $390.0 million upon the achievement of certain commercial milestones, and (iii) pay tiered royalties in the high single-digit to low-teen percentages to Pierre Fabre on worldwide net sales in a given calendar year. Royalties will be payable for each PF Licensed Product in a given country during a period commencing upon the first commercial sale of such PF Licensed Product in such country and continuing until the latest of (a) 10 years after such first commercial sale, (b) expiration of last-to-expire valid claim in a licensed patent in such country and (c) expiration of regulatory exclusivity for such PF Licensed Product in such country. In the event we enter into a sublicense with a third party, we must also share with Pierre Fabre a percentage of any revenues from option fees, upfront payments, license maintenance fees, milestone payments or the like generated from the sublicense. Such percentage may be

between the high single-digits to the low thirties based on which stage of development of a PF Licensed Product the sublicense is entered into.

Unless earlier terminated, the Pierre Fabre Agreement will continue on a PF Licensed Product-by-PF Licensed Product and country-by-country basis until there are no more royalty payments owed to Pierre Fabre on any PF Licensed Product thereunder. Either party may terminate the Pierre Fabre Agreement upon an uncured material breach, or upon the bankruptcy or insolvency of the other party. Pierre Fabre may also terminate the agreement if we or any of our affiliates institutes a patent challenge against the licensed patents from Pierre Fabre. We may also terminate the Pierre Fabre Agreement with or without cause upon nine months' prior written notice, so long as there is no ongoing clinical trial for any PF Licensed Product.

Components of Results of Operations

Operating Expenses

Our operating expenses consist of (i) research and development expenses and (ii) general and administrative expenses.

Research and Development

Research and development expenses consist of external and internal costs primarily related to acquiring our product candidate pipeline and technologies, and clinical development of our product candidates.

External costs include:

- costs associated with acquiring technology and intellectual property licenses that have no alternative future uses and costs incurred under in-license or assignment agreements, including milestone payments;
- costs incurred in connection with the clinical development of our product candidates, including under agreements with CROs, CMOs and other third parties that conduct clinical trials and manufacture clinical supplies, product candidates, and components on our behalf; and
- costs for third-party professional research and development consulting services.

Internal costs include:

- research and development personnel-related costs, including salaries, benefits, travel and meals expenses and stock-based compensation expense; and
- allocated facilities and other overhead costs, including software, computer supplies and accessories and other miscellaneous expenses.

We expense research and development costs as incurred. Costs of certain activities are recognized based on an evaluation of the progress to completion of specific tasks. However, payments made prior to the receipt of goods or services that will be used or rendered for future research and development activities are deferred and capitalized as prepaid expenses and other current assets on our balance sheets. The capitalized amounts are recognized as expense as the goods are delivered or as related services are performed. Since our inception and through December 31, 2022, substantially all of our third-party expenses were related to the development of izokibep. We do not allocate employee costs, laboratory supplies and facilities, including other internal costs, to specific product candidates because these costs are associated with multiple programs and, as such, are not separately classified. We use internal resources primarily for managing our process development, manufacturing, and clinical development activities. We deploy our personnel across all of our research and development activities and, as our employees work across multiple programs, we do not currently track our costs by product candidate indication.

We expect our research and development expenses to increase substantially for the foreseeable future as we advance our product candidates into and through clinical trials, pursue regulatory approval of our product

candidates, build our operational and commercial capabilities for supplying and marketing our products, if approved, and expand our pipeline of product candidates. We expect to incur significant manufacturing costs as our CMOs develop scaled commercial manufacturing processes. The process of conducting the necessary clinical research to obtain regulatory approval is costly and time-consuming. The actual probability of success for our product candidates may be affected by a variety of factors, including the safety and efficacy of our product candidates, clinical data, investment in our clinical programs, competition, manufacturing capability and commercial viability. We may never succeed in achieving regulatory approval for any of our product candidates. As a result of the uncertainties discussed above, we are unable to determine the duration and completion of costs of our research and development projects or if, when and to what extent we will generate revenue from the commercialization and sale of our product candidates, if approved by the FDA and other applicable regulatory authorities.

Our future research and development costs may vary significantly based on factors such as:

- the timing and progress of our preclinical and clinical development activities;
- the number and scope of preclinical and clinical programs we decide to pursue;
- the amount and timing of any milestone payment due under an existing, or any future, license or collaboration agreement;
- the number of patients that participate in our clinical trials, and per participant clinical trial costs;
- the number and duration of clinical trials required for approval of our product candidates;
- the number of sites included in our clinical trials, and the locations of those sites;
- delays or difficulties in adding trial sites and enrolling participants in our clinical trials;
- patient drop-out or discontinuation rates;
- potential additional safety monitoring requested by regulatory authorities;
- the phase of development of our product candidates;
- the efficacy and safety profile of our product candidates;
- the timing, receipt, and terms of any approvals from applicable regulatory authorities including the FDA and non-U.S. regulators, including whether we are permitted to accelerate the development of izokibep for moderate-to-severe HS as well as non-infectious uveitis;
- maintaining a continued acceptable safety profile of our product candidates following approval, if any, of our product candidates;
- changes in the competitive outlook;
- the extent to which we establish additional strategic collaborations or other arrangements; and
- the impact of any business interruptions to our operations or to those of the third parties with whom we work, particularly in light of the current COVID-19 pandemic environment.

A change in the outcome of any of these variables with respect to the development of any of our product candidates could significantly change the costs and timing associated with the development of that product candidate.

General and Administrative

Our general and administrative expenses consist primarily of personnel-related costs, legal and consulting services, including those relating to intellectual property and corporate matters, and allocated overhead, including software, computer supplies and accessories, insurance and other miscellaneous expenses. Personnel-related costs include salaries, annual bonuses, benefits, recruiting fees, travel and meal expenses and stock-based compensation for our general and administrative personnel.

We expect that our general and administrative expenses will increase substantially in the future as a result of expanding our operations, including hiring personnel, preparing for potential commercialization of our product candidates, and facility occupancy costs, as well as various incremental costs associated with operating as a public company. We expect that our costs will increase related to legal, audit, accounting fees, regulatory and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, director and officer insurance costs, investor and public relations costs, and other expenses that we did not incur as a private company. We also expect to increase the size of our administrative function to support the growth of our business.

Other Income (Expense), Net

Other income (expense), net consists primarily of State of Delaware corporate taxes.

Results of Operations

Comparison of the Years Ended December 31, 2021 and 2022

The following table summarizes our results of operations for the years ended December 31, 2021 and 2022 (in thousands):

	Year Ended December 31,		Change	
	2021	2022	$	%
Operating expenses:				
Research and development	$ 38,230	$	$	
General and administrative	3,564			
Total operating expenses	41,794			
Loss from operations	(41,794)			
Other income (expense), net	(45)			
Net loss	$ (41,839)	$	$	

Research and Development Expenses

The following table summarizes our research and development expenses for the years ended December 31, 2021 and 2022 (in thousands):

	Year Ended December 31,		Change	
	2021	2022	$	%
External costs:				
License fee and milestones related to acquired technologies	$ 25,000	$	$	
CRO, CMO and Affibody transition services	10,518			
Professional consulting services	159			
Internal costs:				
Personnel-related costs	2,500			
Facilities and overhead costs	53			
Total research and development expenses	$ 38,230	$	$	

Research and development expenses were $38.2 million for the year ended December 31, 2021.

License fee and milestones related to acquired technologies for the year ended December 31, 2021 include a $25.0 million upfront payment to Affibody for acquired in-process research and development assets and our

exclusive license. CRO, CMO and Affibody transition services were $10.5 million for the year ended December 31, 2021 and include expenses related to the Affibody transition services agreement, pursuant to which we reimbursed Affibody for all development and clinical trial costs related to izokibep. Professional consulting services expenses were $0.2 million for the year ended December 31, 2021 and represented external consulting costs relating primarily to regulatory, clinical and safety matters.

Personnel-related costs were $2.5 million for the year ended December 31, 2021, including stock-based compensation expense of $0.2 million. Facilities and allocated overhead expenses were $0.1 million for the year ended December 31, 2021 and included non-capitalizable computer equipment, software subscriptions and other IT related expenses. We did not lease any facilities during the year ended December 31, 2021.

General and Administrative Expenses

General and administrative expenses were $3.6 million for the year ended December 31, 2021 and primarily consisted of $1.9 million in personnel-related costs, $1.6 million expenses related to legal and other professional consulting services and $0.1 million of IT-related expenses.

Other Income (Expense), Net

Other income (expense), net was approximately $45,000 during the year ended December 31, 2021 related to Delaware corporate tax expense.

Liquidity, Capital Resources and Capital Requirements

Sources of Liquidity

Since our inception, we have not generated any revenue from product sales and have incurred significant operating losses and negative cash flows from our operations. From inception, we have primarily funded our operations from sales of shares of our redeemable convertible preferred stock in private placements.

As of March 31, 2023, we had $ million in cash. Based on our current operating plan, we estimate that our existing cash as of the date of this prospectus, together with the estimated net proceeds from this offering, will be sufficient to fund our projected operating expenses and capital expenditure requirements through at least the next 12 months. We have based this estimate on our current assumptions which may prove to be wrong, and we may exhaust our available capital resources sooner than we expect. Because of the numerous risks and uncertainties associated with therapeutic product development, we may never achieve or maintain profitability and, unless and until we are able to commercialize our product candidates, if ever, we will continue to be dependent upon equity financing, debt financing, and other forms of capital raises. If we are unable to raise capital as and when needed or on attractive terms, we may have to significantly delay, reduce, or discontinue the development and commercialization of our product candidates or scale back or terminate our pursuit of new in-licenses and acquisitions.

Future Funding Requirements

Our primary uses of cash are to fund our operations, which consist primarily of research and development expenditures related to our programs and, to a lesser extent, general and administrative expenditures. We anticipate that we will continue to incur significant and increasing expenses for the foreseeable future as we continue to advance our product candidates, expand our corporate infrastructure, including the costs associated with being a public company, further our research and development initiatives for our product candidates, and incur costs associated with potential commercialization. We are subject to all of the risks typically related to the development of new drug candidates, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business.

Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable, accrued expenses, and prepaid expenses.

Our future funding requirements will depend on many factors, including the following:

- the timing, scope, progress and results of our preclinical studies and clinical trials for our current and future product candidates;
- the number, scope and duration of clinical trials required for regulatory approval of our current and future product candidates;
- the outcome, timing and cost of seeking and obtaining regulatory approvals from the FDA and comparable foreign regulatory authorities for our product candidates, including any requirement to conduct more studies or generate additional data beyond that which we currently expect would be required to support a BLA;
- the cost of manufacturing clinical and commercial supplies of our current and future product candidates;
- the increase in the number of our employees and expansion of our physical facilities to support growth initiatives;
- our ability to maintain existing, and establish new, strategic collaborations, licensing or other arrangements, including our license and collaboration agreements with Affibody and Pierre Fabre, and the financial terms of any such agreements, including the timing and amount of any future milestone, royalty or other payments due under any such agreement;
- the cost of filing and prosecuting our patent applications, and maintaining and enforcing our patents and other intellectual property rights;
- the extent to which we acquire or in-license other product candidates and technologies;
- the cost of defending intellectual property disputes, including patent infringement actions brought by third parties against our product candidates;
- the effect of competing technological and market developments;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;
- the amount of revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive marketing approval;
- our implementation of various computerized informational systems and efforts to enhance operational systems;
- the costs associated with being a public company; and
- the impact of the COVID-19 pandemic, as well as other factors, including economic uncertainty and geopolitical tensions, which may exacerbate the magnitude of the factors discussed above.

Furthermore, our operating plans may change, and we may need additional funds to meet operational needs and capital requirements for clinical trials and other research and development expenditures.

Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through public or private equity or debt financings, or potentially other capital sources, such as collaboration or licensing arrangements with third parties or other strategic transactions. There are no assurances that we will be successful in obtaining an adequate level of financing to support our business plans when needed on acceptable terms, or at all. 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 or could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing and equity 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 collaboration or licensing arrangements with third parties or other strategic transactions, we may have to relinquish rights to our intellectual property, 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 capital as and when needed or on attractive terms, we may have to significantly delay, reduce, or discontinue the development and commercialization of our product candidates or scale back or terminate our pursuit of new in-licenses and acquisitions.

Cash Flows

The following summarizes our cash flows for the periods indicated (in thousands):

	Year Ended December 31,	
	2021	2022
Net cash used in operating activities	$ (4,979)	$
Net cash used in investing activities	(25,000)	
Net cash provided by financing activities	124,720	
Net increase in cash	$ 94,741	$

Operating Activities

Net cash used in operating activities was $5.0 million for the year ended December 31, 2021. Cash used in operating activities in the year ended December 31, 2021 was primarily due to our net loss for the period of $41.8 million, of which $25.0 million is presented as cash used in investing activities as it relates to the acquisition of a license for izokibep and is therefore immediately expensed, and a non-cash charge of $0.2 million related to stock-based compensation expense. The decrease in cash used in operating activities was partially offset by changes in working capital of $11.6 million consisting of an increase of $9.7 million in accrued research and development expenses, an increase of $1.1 million in accounts payable and an increase of $0.9 million in accrued compensation and other current liabilities, all partially offset by an increase of approximately $49,000 in prepaid expenses and other current assets. The increase in accrued research and development expenses and accounts payable were primarily due to costs associated with the development of izokibep.

Investing Activities

Cash used in investing activities for the year ended December 31, 2021 of $25.0 million related to our acquisition of the exclusive license from Affibody.

Financing Activities

Cash provided by financing activities for the year ended December 31, 2021 was primarily related to net proceeds from the issuance of the first tranche of our Series B redeemable convertible preferred stock financing of $124.7 million, and proceeds from exercise of stock options of approximately $16,000.

Contractual Obligations and Commitments

We enter into contracts in the normal course of business with suppliers, CROs, CMOs, clinical trial sites, and the like. These agreements provide for termination at the request of either party generally with less than one-year notice and, therefore, we believe that our non-cancelable obligations under these agreements are not material. We do not currently expect any of these agreements to be terminated and did not have any non-cancelable obligations under these agreements as of December 31, 2021.

We have milestones, royalties, and/or other payments due to third parties under our existing license and collaboration agreements. See Note 3 to our audited financial statements included elsewhere in this prospectus. We could not estimate when such payments will be due and none of these events were probable to occur as of December 31, 2021.

Leases

As of December 31, 2021, we had no outstanding leases.

On January 6, 2023, we entered into an agreement to lease approximately 10,000 square feet of office space located in Agoura Hills, California. The term of the lease is 65 months with an option to extend the term by an additional three-year period. Our total rent commitments under the lease agreement are $1.9 million throughout the lease term. In addition to base rent, we pay our share of operating expenses and taxes.

Recently Issued Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position, results of operations or cash flows is disclosed in Note 2 to our audited financial statements included elsewhere in this prospectus.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported expenses incurred during the reporting periods. On an ongoing basis, we evaluate our estimates and judgments, including but not limited to those related to accrued research and development costs, the fair value of redeemable convertible preferred stock and common stock and stock-based compensation expense, the valuation of deferred tax assets, and uncertain income tax positions. These estimates and assumptions are monitored and analyzed by us for changes in facts and circumstances, and material changes in these estimates and assumptions could occur in the future. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Changes in estimates are reflected in reported results for the period in which they become known. Actual results may differ from these estimates under different assumptions or conditions.

Although our significant accounting policies are described in more detail in Note 2 to our audited financial statements included in this prospectus, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our financial statements.

Accrued Research and Development Expenses

As part of the process of preparing our financial statements, we are required to estimate our accrued research and development expenses, including those related to clinical trials and product candidate manufacturing. This process involves reviewing open contracts and purchase orders, communicating with our applicable 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 services when we have not yet been invoiced or otherwise notified of actual costs. Our service providers invoice us in arrears or require prepayments for services

performed, as well as on a pre-determined schedule or when contractual milestones are met. We make estimates of our accrued expenses as of each balance sheet date in the financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of the estimates with the service providers and make adjustments if necessary. Examples of estimated accrued research and development expenses include fees paid to:

- vendors in connection with preclinical and clinical development activities;
- CROs in connection with clinical trials; and
- CMOs in connection with the process development and scale-up activities and the production of preclinical and clinical trial materials.

Costs for clinical trials and manufacturing activities are recognized based on an evaluation of our vendors' progress towards completion of specific tasks, using data such as participant enrollment, clinical site activations or information provided to us by our vendors regarding their actual costs incurred. Payments for these activities are based on the terms of individual contracts and payment timing may differ significantly from the period in which the services were performed. We determine accrual estimates through reports from and discussions with applicable personnel and outside service providers as to the progress or state of completion of studies, or the services completed. Our estimates of accrued expenses as of each balance sheet date are based on the facts and circumstances known at the time. Costs that are paid in advance of performance are deferred as a prepaid expense and amortized over the service period as the services are provided.

Although we do not expect our estimates to be materially different from amounts actually incurred, our 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. To date, there have not been any material adjustments to our prior estimates of accrued research and development expenses. However, due to the nature of estimates, we cannot assure that we will not make changes to our estimates in the future as we become aware of additional information about the status or conduct of our clinical trials and other research activities.

Asset Acquisitions and Acquired In-Process Research and Development Expenses

We measure and recognize asset acquisitions that are not deemed to be business combinations based on the cost to acquire the asset or group of assets, which includes transaction costs. Goodwill is not recognized in asset acquisitions. In an asset acquisition, the cost allocated to acquire in-process research and development (IPR&D) with no alternative future use is recognized as expense on the acquisition date.

Contingent consideration in asset acquisitions payable in the form of cash is recognized in the period the triggering event is determined to be probable to occur and the related amount is reasonably estimable. Such amounts are expensed or capitalized based on the nature of the associated asset at the date the related contingency is resolved.

We concluded that the exclusive license acquired from Affibody in October 2021 represented an asset acquisition of IPR&D assets with no alternative future use. We further concluded that the arrangement did not qualify as a business combination because substantially all of the fair value of the assets acquired was concentrated in a single asset.

Stock-Based Compensation Expense

Stock-based compensation expense related to the stock-based awards granted to employees, consultants and Board members is measured at the grant date based on the fair value of the award. Compensation expense for

those awards is recognized over the requisite service period, which is generally the vesting period. We use the straight-line method to record the expense of awards with service-based vesting conditions. We account for forfeitures of stock-based awards as they occur rather than applying an estimated forfeiture rate to stock-based compensation expense.

We estimate the fair value of each award on the date of grant using the Black-Scholes option -pricing model. This model requires the use of highly subject assumptions to determine the fair value of each stock-based award, including:

- *Fair value of common stock*. See the subsection titled "—Determination of Fair Value of Common Stock" below.
- *Expected term*. The expected term represents the period that the stock-based awards are expected to be outstanding. The expected term for our stock options was calculated based on the weighted-average vesting term of the awards and the contract period, or simplified method.
- *Expected volatility*. Since we are not yet a public company and do not have any trading history for our common stock, the expected volatility was estimated based on the average historical volatilities of common stock of comparable publicly traded entities over a period equal to the expected term of the stock option grants. The comparable companies were chosen based on their size, stage of their life cycle or area of specialty. We will continue to apply this process until enough historical information regarding the volatility of our stock price becomes available.
- *Risk-free interest rate*. The risk-free interest rate is based on the U.S. Treasury yield in effect at the time of grant for zero-coupon U.S. Treasury notes with maturities approximately equal to the expected term of the awards.
- *Expected dividend yield*. We have never paid dividends on our Class A Common Stock and have no plans to pay dividends on our Class A Common Stock. Therefore, we used an expected dividend yield of zero.

See Note 7 to our audited 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 in the periods presented.

As of December 31, 2022, there was $ million of total unrecognized stock-based compensation expense, respectively, which we expect to recognize over a remaining weighted-average period of years. We expect to continue to grant equity-based awards in the future, and to the extent that we do, our stock-based compensation expense recognized in future periods will likely increase.

The intrinsic value of all outstanding stock options, restricted stock awards (RSAs) and RSUs as of March 31, 2023 was approximately $ million, based on the assumed initial public offering price of $ per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus, of which approximately $ million related to vested stock options, RSAs and RSUs, and approximately $ million related to unvested stock options, RSAs and RSUs.

Determination of Fair Value of Class A Common Stock

As there has been no public market for our Class A Common Stock prior to this offering, the estimated fair value of our Class A Common Stock underlying our stock-based awards has been determined by our board of directors as of each option grant date with input from management, considering our most recently available third-party valuations of Class A Common Stock and our board of directors' assessment of additional objective and subjective factors that it believed were relevant and which may have changed from the date of the most recent valuation through the date of the grant. These third-party valuations were performed in accordance with the guidance outlined in the American Institute of Certified Public Accountants' Accounting and Valuation Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation* (the Practice Aid).

For valuations performed prior to December 31, 2021, in accordance with the Practice Aid, we determined the Option Pricing Method (OPM) was the most appropriate method for determining the fair value of our Class A Common Stock based on our stage of development and other relevant factors. Within the OPM framework, the backsolve method for inferring the total equity value implied by a recent financing transaction involves the construction of an allocation model that takes into account our capital structure and the rights, preferences and privileges of each class of stock, then assumes reasonable inputs for the other OPM variables (expected time to liquidity, volatility and risk-free rate). The total equity value is then iterated in the model until the model output value for the equity class sold in a recent financing round equals the price paid in that round. The OPM is generally utilized when specific future liquidity events are difficult to forecast (i.e., the enterprise has many choices and options available), and the enterprise's value depends on how well it follows an uncharted path through the various possible opportunities and challenges. In determining the estimated fair value of the Class A Common Stock, our board of directors also considered the fact that the stockholders could not freely trade the Class A Common Stock in the public markets. Accordingly, we applied discounts to reflect the lack of marketability of its Class A Common Stock based on the weighted-average expected time to liquidity. The estimated fair value of the Class A Common Stock at each grant date reflected a non-marketability discount partially based on the anticipated likelihood and timing of a future liquidity event.

For valuations performed after December 31, 2021 in accordance with the Practice Aid, we determined the hybrid method was the most appropriate method for determining the fair value of our Class A Common Stock based on our stage of development and other relevant factors. The hybrid method is a probability-weighted expected return method (PWERM), where the equity value in one or more scenarios is calculated using an OPM. The PWERM is a scenario-based methodology that estimates the fair value of Class A Common Stock based upon an analysis of future values for the company, assuming various outcomes. The Class A Common Stock value is based on the probability-weighted present value of expected future investment returns considering each of the possible outcomes available as well as the rights of each class of stock. The future value of the Class A Common Stock under each outcome is discounted back to the valuation date at an appropriate risk-adjusted discount rate and probability weighted to arrive at an indication of value for the Class A Common Stock. A discount for lack of marketability of the Class A Common Stock is then applied to arrive at an indication of value for the Class A Common Stock.

In addition to considering the results of independent third-party valuations, our board of directors considered various objective and subjective factors to determine the fair value of Class A Common Stock as of each grant date, including:

- the prices at which we sold shares of our preferred stock and the superior rights, preferences and privileges of our preferred stock relative to those of our Class A Common Stock at the time of each grant;
- the progress of our research and development programs, including the status of preclinical studies and clinical trials for our product candidates;
- our stage of development and our business strategy, and material risks related to our business;
- external market conditions affecting the biotechnology industry and trends within the biotechnology industry;
- the competitive landscape for our product candidates;
- our financial position, including cash on hand, and our historical and forecasted performance and operating results;
- the lack of an active public market for our Class A Common Stock and our preferred stock;

- the likelihood of achieving a liquidity event, such as an initial public offering (IPO) or a sale of our company, given prevailing market conditions; and
- the economy in general.

We also performed a retrospective review of Class A Common Stock fair value when preparing for our financial statements audits and considered the amount of time between the independent third-party valuation dates and the grant dates. We performed an interpolation of the fair value between the two valuation dates if we concluded that a significant change in valuation had occurred between the previous valuation and the grant date due to significant business or market events. The incremental stock-based compensation expense recorded as a result of the retrospective review was insignificant.

The assumptions underlying these valuations represented management's best estimate, 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 be materially different.

Once a public trading market for our Class A Common Stock has been established in connection with the completion of this offering, it will no longer be necessary for our board of directors to estimate the fair value of our Class A Common Stock in connection with our accounting for granted stock options and other such awards we may grant, as the fair value of our Class A Common Stock will be based on the quoted market price of our common stock.

Off-Balance Sheet Arrangements

During the periods presented we did not have, nor do we currently have, any off-balance sheet arrangements as defined in the rules and regulations of the SEC.

Quantitative and Qualitative Disclosures About Market Risks

Interest Rate Risk

The primary objectives of our investment activities are to ensure liquidity and to preserve capital. We are exposed to market risks related to changes in interest rates of our cash equivalents and short-term investments. However, due to the nature of these cash equivalents and investments, we do not believe that a hypothetical 10% increase or decrease in interest rates during any of the periods presented would have had a material effect on our financial statements included elsewhere in this prospectus.

Foreign Currency Exchange Risk

All of our employees and our operations are currently located in the United States and our expenses are generally denominated in U.S. dollars. However, we do utilize certain CMO vendors outside of the United States for our manufacturing of drug substances and clinical supplies. As such, our expenses are denominated in both U.S. dollars and foreign currencies. Therefore, our operations are and will continue to be subject to fluctuations in foreign currency exchange rates. To date, foreign currency transaction gains and losses have not been material to our financial statements, and we have not had a formal hedging program with respect to foreign currency. We do not believe that a hypothetical 10% increase or decrease in exchange rates during any of the periods presented would have had a material effect on our financial statements included elsewhere in this prospectus.

Effects of Inflation

Inflation generally affects us by increasing our cost of labor and research and development costs. We do not believe that inflation had a material effect on our business, results of operations, or financial condition, or on our financial statements included elsewhere in this prospectus.

Internal Control Over Financial Reporting

In connection with the preparation of our financial statements for the year ended December 31, 2021, we identified material weaknesses in the design and operating effectiveness of our internal control over financial reporting related to the fact that we lacked a sufficient number of professionals to consistently establish appropriate authorities and responsibilities in pursuit of our financial reporting objectives. The lack of sufficient number of finance and accounting professionals further contributed to the following additional material weaknesses. We did not design and maintain an effective risk assessment process at a precise enough level to identify new and evolving risks of material misstatement in the consolidated financial statements. Additionally, we did not design and maintain effective controls over the segregation of duties related to journal entries and account reconciliations. Specifically, certain personnel had the ability to both (i) create and post journal entries within the company's general ledger system and (ii) prepare and review account reconciliations without a review performed by someone without conflicting duties.

There were no adjustments that resulted from the above material weaknesses. However, these material weaknesses could result in a misstatement of substantially all of our accounts or disclosures that would result in a material misstatement of our annual or interim financial statements that would not be prevented or detected.

To remediate the material weaknesses, we have begun to hire additional accounting personnel, as well as have engaged a third-party firm to assist in the design and implementation of controls. We are in the process of implementing a formal risk assessment process and procedures and designing sufficient controls to remediate these weaknesses. We intend to continue to take steps to remediate these material weaknesses through the hiring of additional experienced accounting and financial reporting personnel, formalizing documentation of policies and procedures and further evolving the accounting processes, including implementing appropriate segregation of duties. The material weaknesses will not be considered remediated until management completes the design and implementation of the measures described above and the controls operate for a sufficient period of time and management has concluded, through testing, that these controls are effective.

Emerging Growth Company Status

We qualify as an "emerging growth company," as defined in the JOBS Act. As an emerging growth company, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies. These provisions include: (i) being permitted to present 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 in this prospectus; (ii) reduced disclosure about our executive compensation arrangements; (iii) not being required to hold advisory votes on executive compensation or to obtain stockholder approval of any golden parachute arrangements not previously approved; (iv) an exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act of 2002; and (v) an exemption from compliance with the requirements of the Public Company Accounting Oversight Board regarding the communication of critical audit matters in the auditor's report on the financial statements.

We may take advantage of these exemptions for up to five years or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company on the date that is the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of $1.24 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of the date of the completion of this offering; (iii) the date on which we have issued more than $1.0 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC. We may choose to take advantage of some but not all of these exemptions. We have taken advantage of reduced reporting requirements in this prospectus. Accordingly, the information contained herein may be different from the information you receive from other public companies in which you hold stock. Additionally, the JOBS

Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this exemption and, therefore, while we are an emerging growth company we will not be subject to new or revised accounting standards at the same time that they become applicable to other public companies that are not emerging growth companies. As a result of this election, our financial statements may not be comparable to those of other public companies that comply with new or revised accounting pronouncements as of public company effective dates. We may choose to early adopt any new or revised accounting standards whenever such early adoption is permitted for private companies.

BUSINESS

Overview

ACELYRIN is a late-stage clinical biopharma company focused on identifying, acquiring, and accelerating the development and commercialization of transformative medicines. We are driven by our sense of urgency to bring life-changing therapies to patients globally, a core value that we refer to as "courageous caring."

Our initial focus is on the treatment of diseases with pathology related to excess activation of the immune system, an area where our management and team bring industry-leading expertise. We acquired our portfolio of product candidates with the intent to develop and commercialize novel therapies that we believe provide the opportunity to offer clinically meaningful, differentiated benefits for patients by improving upon the efficacy and/or safety of existing therapeutics directed against established targets, such as currently marketed anti-interleukin (IL)-17A agents, or by targeting new modalities. In each case, our strategy is to identify candidates we believe are "diamonds in the rough," where, based on molecule characteristics, our collective experience and expertise, and the evolving scientific and medical understanding, we can establish a clinical development plan that tests our hypotheses as to what those novel benefits could mean for patients. Subsequently, we utilize the results we obtain in initial clinical trials and the learnings we obtain from emerging biology to expand the application of our candidates to other indications in which there are significant unmet needs.

Our current portfolio consists of multiple clinical and preclinical stage candidates being investigated across several indications and representing multi-billion-dollar opportunities in the aggregate.

Our lead product candidate is izokibep, a small protein therapeutic designed to inhibit IL-17A with higher potency through exponentially higher binding affinity and the potential for greater tissue penetration compared to traditional monoclonal antibodies due to its markedly smaller size. In numerous clinical trials, izokibep has demonstrated clinically meaningful benefits and is currently in development for multiple immunological indications including hidradenitis suppurativa (HS), psoriatic arthritis (PsA), axial spondyloarthritis (AxSpA) and uveitis. Izokibep has been administered to more than 400 participants, including at doses up to 160 mg, and in some for up to three years, and has generally been well-tolerated with a safety profile consistent with that of the anti-IL-17A class as a whole.

We recently announced achieving higher orders of clinical response in Part A of our Phase 2b/3 trial of izokibep in HS, which we believe supports the potential to offer clinically meaningful, differentiated benefit to participants in this severe autoimmune condition where the hallmark of disease is skin abscesses, nodules, fistulae and scar tissue. Clinical responses in this open label portion of our ongoing trial in HS were demonstrated at levels where placebo responses historically have been low to none.

We have also presented results from a randomized, placebo-controlled Phase 2 trial of izokibep in PsA, which demonstrated differentiated clinical outcomes relative to available therapies, especially in the difficult to treat entheseal tissues, where unchecked inflammation (enthesitis) is a marker of disease severity and is often associated with residual pain and physical dysfunction, negatively impacting quality of life.

These results from our trials in HS and PsA offer two independent sets of clinical data supporting our hypothesis that izokibep could offer clinically meaningful, differentiated outcomes due to its high potency and small size, and therefore the potential to provide greater benefit to patients, especially in diseases with historically difficult-to-treat tissues where significant residual unmet needs exist.

As a result of the encouraging data in HS and PsA, we have prioritized development in those indications. For HS, in addition to the ongoing trial below, we are planning to initiate a second Phase 3 trial. For PsA, we accelerated into 2022 the initiation of a Phase 2b/3 trial evaluating a range of doses, including significantly higher doses than the Phase 2 trial. The trials we are currently enrolling with izokibep are a:

- Phase 2b/3 trial of izokibep in HS;

- Phase 2b/3 trial of izokibep in PsA; and
- Phase 2b/3 trial of izokibep in uveitis.

Additionally, we plan to initiate two Phase 3 trials in AxSpA based on dosing data from the ongoing PsA Phase 2b/3 trial. Enthesitis is a key feature of AxSpA, and central to the progression of the disease. Therefore, we believe the benefits of izokibep on enthesitis demonstrated in PsA could be even more meaningful for patients with AxSpA.

We plan to seek orphan drug designation from the relevant regulatory authorities for both moderate-to-severe HS, as well as non-infectious uveitis. In each case, assuming this orphan designation is granted, and subject to discussions with the relevant regulatory authorities, we are conducting the ongoing Phase 2b/3 trials in these indications to enable inclusion in a future registrational package, potentially requiring only one confirmatory Phase 3 clinical trial for each indication.

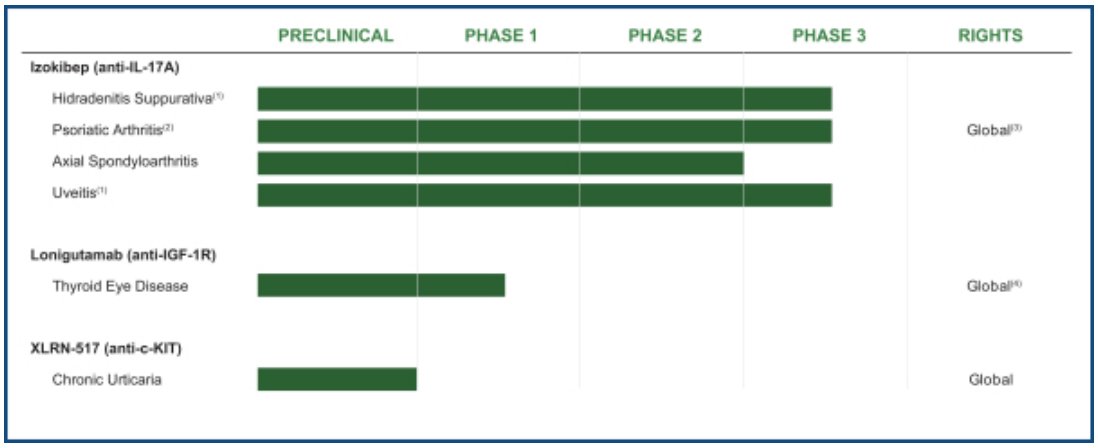
We are equally excited by the potential of our earlier-stage pipeline which includes both clinical and preclinical assets.

We are also advancing lonigutamab, a humanized immunoglobulin G1 (IgG1) monoclonal antibody against insulin-like growth factor 1 receptor (IGF-1R). Lonigutamab has been shown to be markedly more potent than the currently marketed therapy for thyroid eye disease (TED) in both binding and functional laboratory assays. We believe that these characteristics, along with subcutaneous dosing, may offer the potential for differentiated benefits in TED relative to the standard of care. For efficacy, we will evaluate the opportunity to achieve greater depth and durability of response, and for safety, the opportunity to dose in a manner that could mitigate the on-target side effects of the only currently approved therapeutic, including hearing impairment. Data from the single ascending dose (SAD) portion of the Phase 1 trial in healthy volunteers will be presented at the 2023 North American Neuro-Ophthalmology Society meeting and the multiple ascending dose (MAD) portion of this trial in TED is currently recruiting.

In addition, we are developing XLRN-517, which is a fully human IgG1 monoclonal antibody targeting c-KIT. The inhibition of c-KIT reduces mast cell proliferation and activity in various allergy and inflammatory diseases. XLRN-517 aims to address the root cause of mast cell driven diseases by blocking mast cell proliferation and degranulation. XLRN-517 is designed as a highly potent inhibitor (antagonism) of the c-KIT pathway, targeting mast cell proliferation and degranulation, without stimulating (agonism) mast cell degranulation. XLRN-517 has lower potential for immunogenicity relative to monoclonal antibodies that are not fully human. The picomolar (pM) binding affinity and cell based functional potency of XLRN-517 offer the potential for low volume subcutaneous dosing. We believe these distinct characteristics may enable us to better determine the full extent of involvement of mast cell biology in chronic urticaria as well as other diseases where mast cells may play a central role. We believe monoclonal antibodies have the potential to offer safety and efficacy advantages over small molecule inhibitors of the c-KIT pathway.

Like izokibep and lonigutamab, we believe XLRN-517 has the potential to address multiple indications, including other mast cell driven disorders beyond chronic urticaria, such as prurigo nodularis, bullous pemphigoid and eosinophilic esophagitis.

Our Pipeline



(1) Phase 2b/3 trial in moderate-to-severe HS and uveitis. Planned inclusion into registrational package for HS and non-infectious uveitis (as applicable) if granted orphan drug designation and following consultation with relevant heath authorities.
(2) Phase 2b/3 trial in PsA.
(3) Excludes development, commercialization and manufacturing rights in mainland China, Hong Kong, Macau, South Korea and Taiwan, and development rights in certain other Asia Pacific countries. We retain decision making authority for izokibep global development. See the section titled "Business—License and Collaboration Agreements" for further information.
(4) Worldwide rights to non-oncology indications. See the section titled "Business—License and Collaboration Agreements" for further information.

Our Team and Investors

Our company is led by Shao-Lee Lin, M.D., Ph.D., our Founder and Chief Executive Officer. Prior to founding our company, Dr. Lin was the first Chief Scientific Officer at Horizon Therapeutics plc, where she led research and development, including the development and approval of teprotumumab for the treatment of TED. Prior to Horizon, she held multiple positions at AbbVie Inc., most recently leading Therapeutic Areas, Development Excellence and International Development and initially as Vice President, Global Immunology and Renal Development. Prior to AbbVie, Dr. Lin served as Vice President, Inflammation and Respiratory Development at Gilead Sciences Inc. and served in various roles of increasing responsibility at Amgen Inc. Dr. Lin has been faculty as a Clinical Scholar at The Rockefeller University and adjunct faculty at the medical schools of Cornell University, The University of California, Los Angeles (UCLA), Stanford University and Northwestern University. Dr. Lin is joined by a team of veteran biopharma executives who together bring exceptional track records of identifying, acquiring, and then rapidly and robustly developing and commercializing medicines. These leaders were instrumental in achieving the first approvals, or expanded indications, for transformative therapies including Humira, Tepezza, Rinvoq, Skyrizi, Mavyret and Enbrel, that have provided clinically meaningful and differentiated benefit for patients. These therapies have subsequently become some of the most successful medicines within the biopharmaceutical industry.

Since our inception we have secured more than $550 million in committed capital, of which over $400 million has already been funded and $150 million will be funded, subject to certain conditions, by our Series C preferred stock investors if this offering is not completed by June 30, 2023.

Our Strategy

Our vision is to build a leading integrated biopharma company focused on delivering transformative medicines to patients. Immunology is an area of deep core expertise throughout the organization, and therefore is our area of initial focus. Our mission is to identify, acquire, and accelerate the development and

commercialization of medicines that we believe have the potential to offer clinically meaningful, differentiated benefits to patients. We intend to achieve that goal by implementing the following strategies.

- **Maximize the value of izokibep.** Izokibep is a "pipeline-in-a-program" with promising clinical data obtained in multiple immunology-related indications. Clinical data generated to date support our hypothesis that the high *in vitro* potency and small molecular size of izokibep hold the potential for differentiated efficacy in diseases such HS, PsA, AxSpA and uveitis, and we plan to advance these opportunities in parallel clinical trials. In addition, we intend to explore the potential development of izokibep in future indications where there is strong rationale for IL-17A inhibition and high unmet patient need.
- **Advance lonigutamab for the treatment of TED.** Lonigutamab is a potent anti-IGF-1R in development for the treatment of TED, with potentially improved efficacy, safety and dosing convenience compared to currently available treatment options. Pharmacokinetic (PK) and pharmacodynamic (PD) data from subcutaneous dosing in healthy volunteers in the SAD portion of our ongoing Phase 1 trial and differentiated preclinical data highlight the potential of lonigutamab to greatly expand and transform the treatment of TED. Many on our team bring prior experience in this field, which provides us with insights we believe are important in the development of lonigutamab for TED.
- **Advance earlier stage product candidates into clinical development.** We intend to expand our pipeline of clinical stage product candidates by identifying and developing earlier stage candidates. For example, we are developing XLRN-517, a fully human monoclonal antibody designed to target a distinct epitope of c-KIT, that we anticipate bringing into the clinic for the treatment of chronic urticaria and exploring its potential in other mast cell-driven indications.
- **Diversify our portfolio with new product candidates**. Our ability to identify, acquire and rapidly advance izokibep into late-stage clinical trials across several indications exemplifies the approach that we are actively pursuing to continue to diversify our portfolio with drug candidates that fit our strategic focus. Specifically, we plan to acquire and advance new therapies where we feel we can offer unique experience and expertise to optimize their development and value.
- **Evaluate strategic collaborations**. We believe that our team's experience and track record demonstrate ACELYRIN's capabilities and make our company an attractive partner. We will strategically evaluate potential collaborations to maximize the value of our portfolio.
- **Build our operational and commercial capabilities for supplying and marketing our products, if approved, in key markets.** In general, we intend to manage our products from development through to commercialization. Where beneficial, we may collaborate with a partner for various capabilities such as manufacturing, marketing and/or sales of our products in one or more geographies. With late-stage trials underway for izokibep in multiple indications, we remain committed to continuing to build the capabilities necessary to achieve our goal of becoming an integrated biopharma company.

Our Izokibep (Small Protein IL-17A Inhibitor) Program

Summary Overview of Izokibep

Our lead product candidate is izokibep, a small protein therapeutic designed to inhibit IL-17A with higher potency through exponentially higher binding affinity and the potential for greater tissue penetration compared to traditional monoclonal antibodies due to its markedly smaller size.

In numerous clinical trials, izokibep has demonstrated clinically meaningful and differentiated benefits and is currently in development for multiple immunological indications including HS, PsA, AxSpA and uveitis. Izokibep has been administered to more than 400 participants, including at doses up to 160 mg, and in some for up to three years. Izokibep has generally been well-tolerated with a safety profile consistent with that of the anti-IL-17A class as a whole.

Izokibep has demonstrated higher orders of clinical response in Part A of our Phase 2b/3 trial in HS, which we believe supports the potential to offer clinically meaningful, differentiated benefits to participants with this severe autoimmune condition where the hallmark of disease is skin abscesses, nodules, fistulae and scar tissue. Clinical responses in Part A of our trial in HS were demonstrated at higher orders of Hidradenitis Suppurativa Clinical Response (HiSCR) where placebo response rates historically have been low-to-none. We have also shared results from a randomized, placebo-controlled Phase 2 trial of izokibep in PsA, which demonstrated differentiated clinical outcomes relative to available therapies. This was particularly evident in the difficult to treat entheseal tissues, where unchecked inflammation (enthesitis) is a marker of disease severity and is often associated with residual pain and physical dysfunction, negatively impacting quality of life. These results from our trials in HS and PsA offer two independent sets of clinical data supporting our hypothesis that izokibep could offer clinically meaningful, differentiated outcomes due to its high potency and small size, and therefore the potential to provide greater benefit to patients, especially in diseases with historically difficult to treat tissues where significant unmet needs remain.

As a result of our encouraging data in HS and PsA, we have prioritized development in these indications. For HS, in addition to the ongoing trial below, we plan to begin a second Phase 3 trial. For PsA, we accelerated into 2022 the initiation of a Phase 2b/3 trial evaluating a range of doses, including significantly higher doses than the Phase 2 trial based on our modeling that suggests that increasing duration of treatment and higher doses could result in continued improvement of clinical outcomes. The trials we are currently enrolling with izokibep are a:

- Phase 2b/3 trial of izokibep in HS;
- Phase 2b/3 trial of izokibep in PsA; and
- Phase 2b/3 trial of izokibep in uveitis.

Additionally, we are planning to initiate two Phase 3 trials in AxSpA based on dosing data from the ongoing PsA Phase 2b/3 trial. Enthesitis is a key feature of AxSpA, and central to the progression of the disease. Therefore, we believe the benefits of izokibep on enthesitis demonstrated in PsA could be even more meaningful for patients with AxSpA.

We plan to seek orphan drug designation from the relevant regulatory authorities for both moderate-to-severe HS as well as non-infectious uveitis. In each case, assuming this orphan designation is granted, and subject to discussions with the relevant regulatory authorities, we are conducting the ongoing Phase 2b/3 trials in these indications to enable inclusion in a future registrational package, potentially requiring only one confirmatory Phase 3 clinical trial for each indication.

Interleukin-17A, a Clinically Validated Target

Due to the central role of IL-17 in driving the expression of other proinflammatory cytokines and the recruitment of immune cells, down-regulating it with a biologic can lead to broad anti-inflammatory activity. The IL-17 family consists of at least six structurally similar cytokines, named IL-17A through IL-17F. Amongst them, IL-17A and IL-17F are known to drive inflammation and host defense by inducing secretion of proinflammatory cytokines, chemokines and antimicrobial peptides via IL-17 receptor A and receptor C.

While IL-17A and IL-17F are both required for mucosal immunity, IL-17A plays a more critical role in inflammation and autoimmunity. IL-17A induces additional proinflammatory cytokines and chemokines through its interaction with both the myeloid cells and a subset of T cells, unlike IL-17F. IL-17 receptor A binds with an extremely low affinity to IL-17F, whereas IL-17 receptor C binds with higher affinity to IL-17F than to IL-17A, leading to distinct downstream immune effects.

While IL-17A inhibition alone has been clinically validated to reduce inflammation, with the approval of secukinumab and ixekizumab, IL-17F inhibition alone has been shown to have minimal effect. Simultaneous blockade of IL-17A and IL-17F has been shown to be associated with dose-dependent increased risk of infection, especially fungal infections.

Immune dysregulation driven by IL-17A has been identified as a driver of inflammation in many autoimmune and inflammatory diseases. These include PsA, HS, AxSpA, uveitis and psoriasis (PsO). In each of these diseases, elevated levels of IL-17A are found in patient's sera, and in skin diseases, such as PsO, at lesion sites.

Our Solution: Izokibep

Izokibep is Highly Differentiated from Monoclonal Antibodies

Izokibep is a small protein therapeutic designed to bind the homodimeric IL-17A molecule with high potency. In contrast to conventional monoclonal antibodies, which are multi-subunit proteins, izokibep is much smaller – approximately one-tenth the size of a traditional monoclonal antibody – containing two IL-17A binding domains and an albumin binding domain that results in improved PK properties.

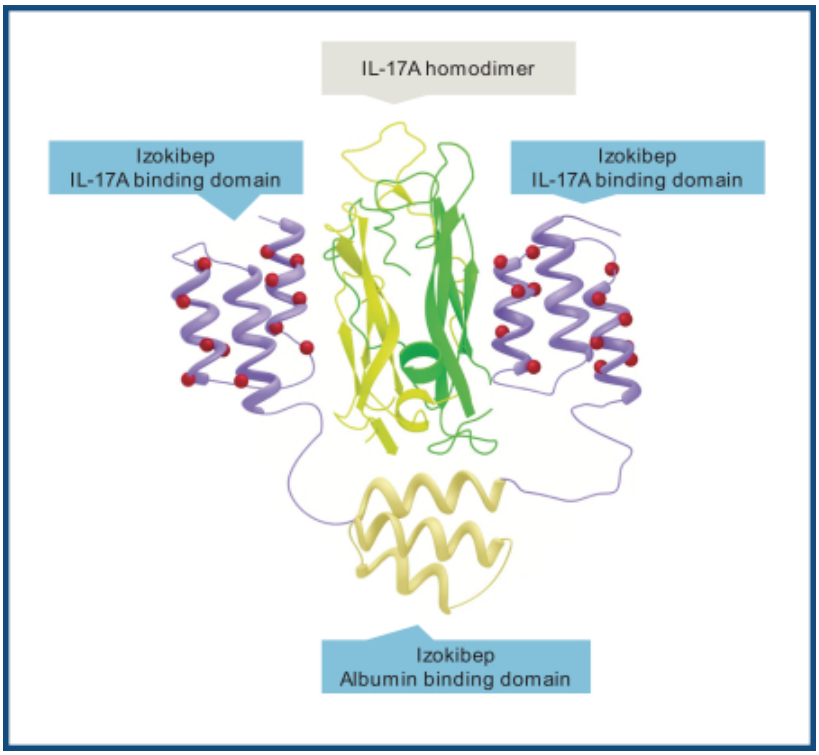


Figure 1. Structural model of izokibep binding to IL-17A homodimer.

By virtue of its structure and size, we believe izokibep has several key potential advantages over traditional monoclonal antibodies:

- **Enhanced potency**. Izokibep binds both subunits of the IL-17A dimer simultaneously, resulting in complete blockade of IL-17 signaling in preclinical studies as shown in the Figure 2(a). Izokibep is highly potent with a dissociation constant (K_D) of 0.3 pM to human IL-17A, compared to currently U.S. Food and Drug Administration (FDA)-approved anti-IL-17A agents secukinumab, which has a K_D of 200 pM and ixekizumab, which has a K_D of 1.8 pM. Indeed, the increased *in vitro* potency translated to the ability of izokibep to inhibit IL-17 signaling in a murine model at approximately 30- to 50-fold lower dose than that required for secukinumab or ixekizumab, as shown in Figure 2(b).

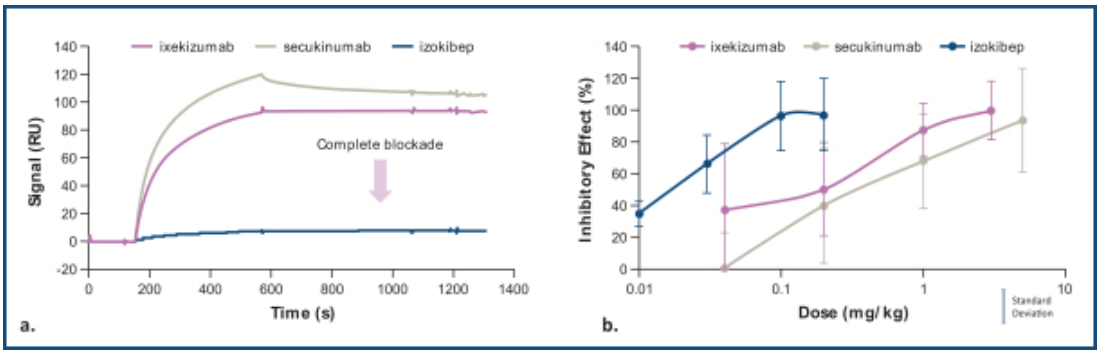


Figure 2. Izokibep (a) demonstrated complete blockade of IL-17A signaling cascade and (b) inhibited IL-17A signaling at markedly lower dose levels compared to secukinumab and ixekizumab in a murine model.

- **Albumin-binding domain provides half-life extension and improved tissue exposure**. The albumin-binding domain increases the plasma half-life of izokibep and enhances its ability to target sites of inflammation including difficult to penetrate spaces such as those surrounding the entheses.

- **Smaller size improves tissue penetration**. Izokibep is approximately one-tenth the size of a traditional monoclonal antibody, enabling the potential to reach poorly vascularized tissues that are difficult to access with traditional monoclonal antibodies. In murine skin, izokibep demonstrated greater exposure, increasing over time, compared to secukinumab, as shown in Figure 3 below.

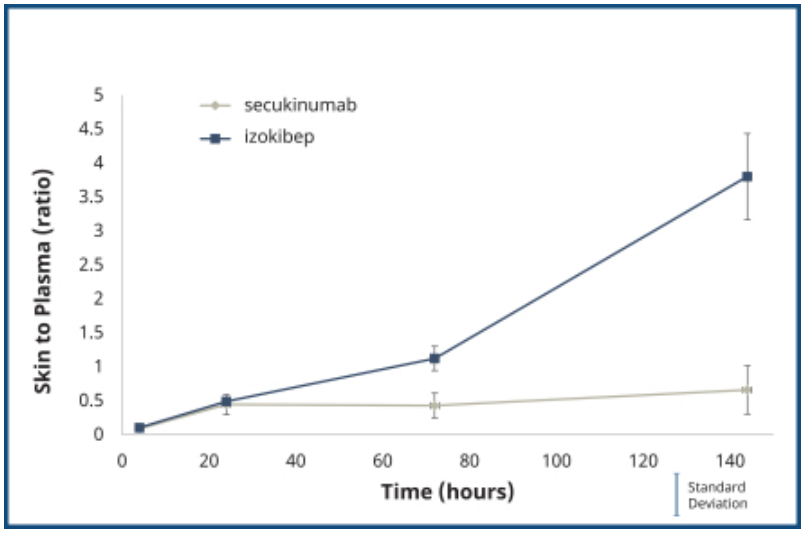


Figure 3. Superior skin exposure of izokibep in mice.

- **Potential to deliver higher exposures more conveniently**. The lower molecular weight of izokibep (18.6 kDa) compared to traditional monoclonal antibodies (~150 kDa) means that there are more izokibep drug molecules, and potentially more potent molecules, in the same injection volume. As a result, we believe izokibep can deliver comparable exposures in a single subcutaneous injection compared to what is currently delivered via intravenous (IV) infusion with monoclonal antibodies.

Izokibep for the Treatment of Moderate-to-Severe HS

HS is a chronic, scarring, painful and debilitating inflammatory skin disease characterized by occlusion of hair follicles in sweat glands. These inflamed areas are often colonized by bacteria leading to further inflammation and initiating a chronic cycle of inflammation, healing, and scarring. Inflammation can lead to inflamed nodules and abscesses due to draining skin tunnels and bands of severe scarring. HS typically occurs in areas with high concentrations of sweat glands and where skin folds touch or rub together such as the arm pit, groin, perianal region and under the breast.

HS is typically accompanied by pain, malodor, drainage, and disfigurement that contribute to disability and a devastating impact on quality of life. Patients with HS miss a greater number of days of work and have increased disability compared to the average population. Pain from HS nodules and abscesses may cause sleep disturbance, limit function, and induce psychological distress. HS and the embarrassment associated with the body odor it causes typically has a tremendous psychological impact on patients, which often affects many facets of their life and promotes isolation due to fear of stigmatization. One in six HS patients report being hospitalized and one in four have visited the emergency department four or more times for acute symptoms. Suicidal ideation or suicidal attempts in the patient population are high with some estimates of suicidal ideation as high as 9%.

The severity of HS is stratified using the three-stage Hurley clinical staging system. In Hurley Stage I, abscesses are present without skin tunnels or scarring. In Hurley Stage II is characterized by recurrent abscesses with tunnels and scarring. In Hurley Stage III, there are multiple interconnected skin tunnels extending across a large area.

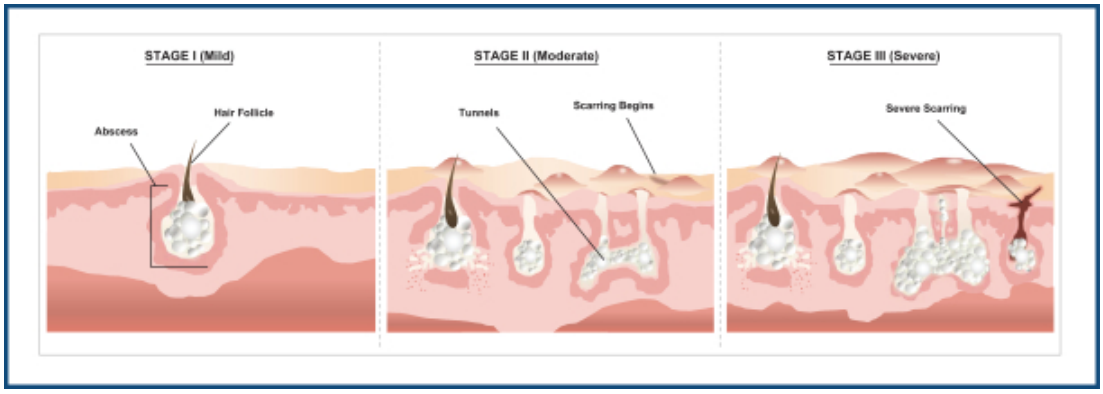


Figure 4. Illustration of three stages of HS.

HS is generally treated symptomatically with intra-lesional glucocorticoid injections or short-term pulse oral glucocorticoids, antibiotics and surgery. Efficacy of treatments in HS is typically measured by improvements in HiSCR. HiSCR is a clinically validated scoring system that is used to assess disease and which was accepted as a valid clinical endpoint included in the regulatory approval process for the only approved therapy for HS, adalimumab (marketed as Humira). HiSCR50 represents a 50% improvement in abscesses and nodules. Higher order responses, such as 75% improvement (HiSCR75) or 90% improvement (HiSCR90), represent even greater clinical benefit, but are uncommonly achieved results. Results from the adalimumab registrational clinical trials demonstrated HiSCR50 for approximately half of patients with moderate-to-severe HS. Notably, of those who responded, approximately half lost response within one year.

In 2019, there were an estimated 317,000 HS patients in the United States, of which 50-60% were moderate-to-severe HS patients and approximately 25,000 to 30,000 of them were treated with adalimumab. Adalimumab was granted Orphan Drug Designation for moderate-to-severe HS. Based on market research conducted for us by Skysis, a member of Fishawack Health (Skysis), the total market globally for the treatment of HS in 2022 was approximately $1.2 billion and is expected to grow to approximately $2.9 billion by 2030.

Targeting IL-17A in the Treatment of HS

High serum levels of IL-17A have been found in HS patients and these levels are correlated with the severity of inflammation. The fundamental role of high levels of IL-17A in bridging the innate and adaptive immune system, and in stimulating the expression of proinflammatory cytokines, is well recognized and has driven clinical trials with anti-IL-17 biologics in HS.

Recent positive results from Phase 3 trials of secukinumab and bimekizumab, respectively, in HS validated the therapeutic potential of IL-17 inhibition in this disease. Results from two Phase 3 trials of secukinumab were reported at the 2022 European Academy of Dermatology and Venereology (EADV) Congress, as shown in Figure 5 below. Treatment with 300 mg secukinumab every two or four weeks for 16 weeks led to achievement of HiSCR50 in 42% to 46% of participants versus the 31% to 34% observed with placebo.

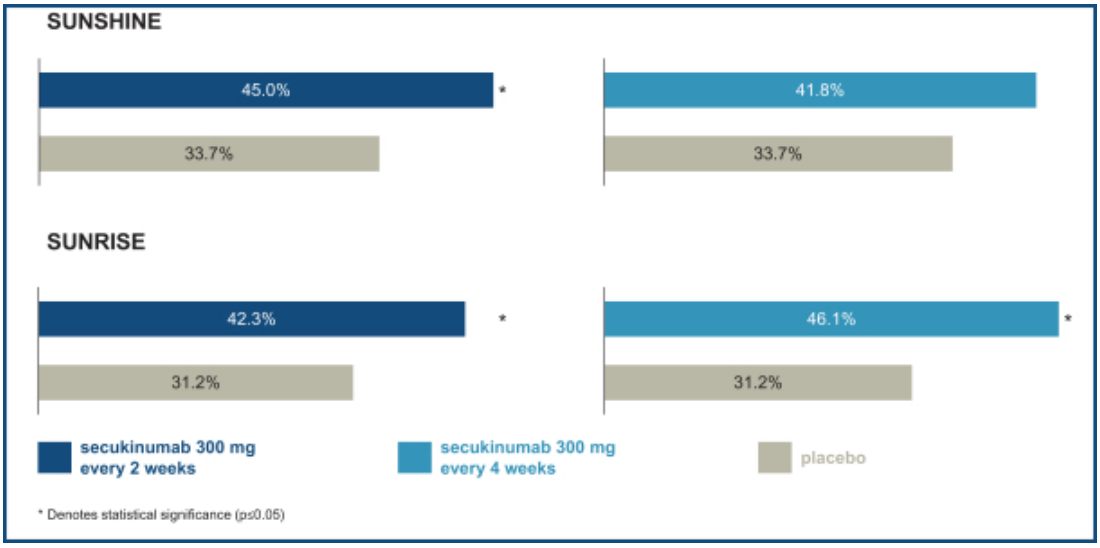


Figure 5. Results from the SUNSHINE AND SUNRISE Phase 3 trials of secukinumab in HS demonstrated significant improvements at Week 16. Percent of participants who achieved a HiSCR50 are shown.

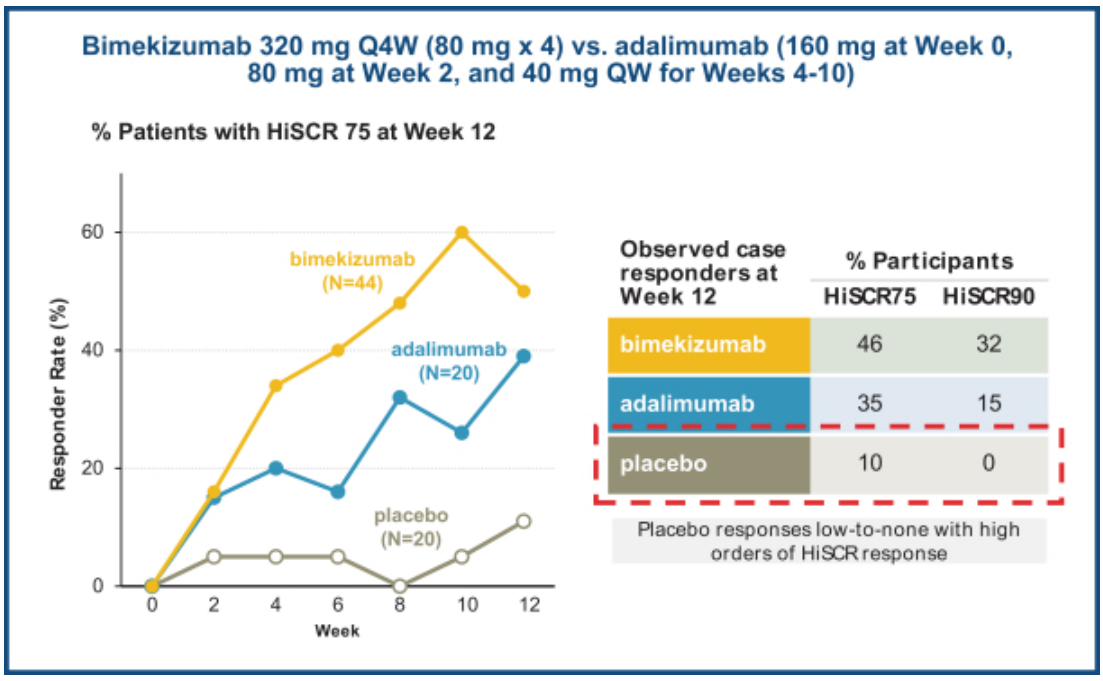


Figure 6. Results from the Phase 2 trial evaluating bimekizumab compared to adalimumab and placebo in HS. Percent of participants who achieved HiSCR75 and HiSCR90 response over 12 weeks are shown.

We believe these results validate the use of IL-17A inhibitors for the treatment of HS while highlighting a substantial opportunity for IL-17A inhibitors that may have higher potency to improve response rates.

In addition to the bimekizumab Phase 2 data, as shown in Figure 6 above, in December 2022 UCB S.A. (UCB) announced that in two Phase 3 trials bimekizumab demonstrated statistically significant improvements over placebo in the proportion of patients who achieved HiSCR50 and HiSCR75 at Week 16. UCB also reported that the safety profile of bimekizumab in both studies was consistent with previously reported trials, which included a 9% candida infection rate in the Phase 2 trial.

Limitation of Current Treatment for HS

We believe that the rates of clinical response to both adalimumab and secukinumab are limited by the inability to achieve optimal dosing in HS patients at currently approved subcutaneous doses. In the case of adalimumab, as shown in Figure 7 below, serum drug concentrations in HS patients were approximately half of those observed in a matched-cohort of PsO patients despite more frequent dosing. We believe this is likely to have limited the clinical activity of adalimumab in HS patients as evidenced by the increased clinical activity observed when the dose of adalimumab was doubled. Subcutaneous doses of 300 mg of secukinumab once every two weeks (Q2W) achieved results similar to adalimumab and require two 1 ml injections every two weeks, but delivering higher secukinumab drug levels via additional subcutaneous administration would further increase the burden on patients through frequent multiple injections.

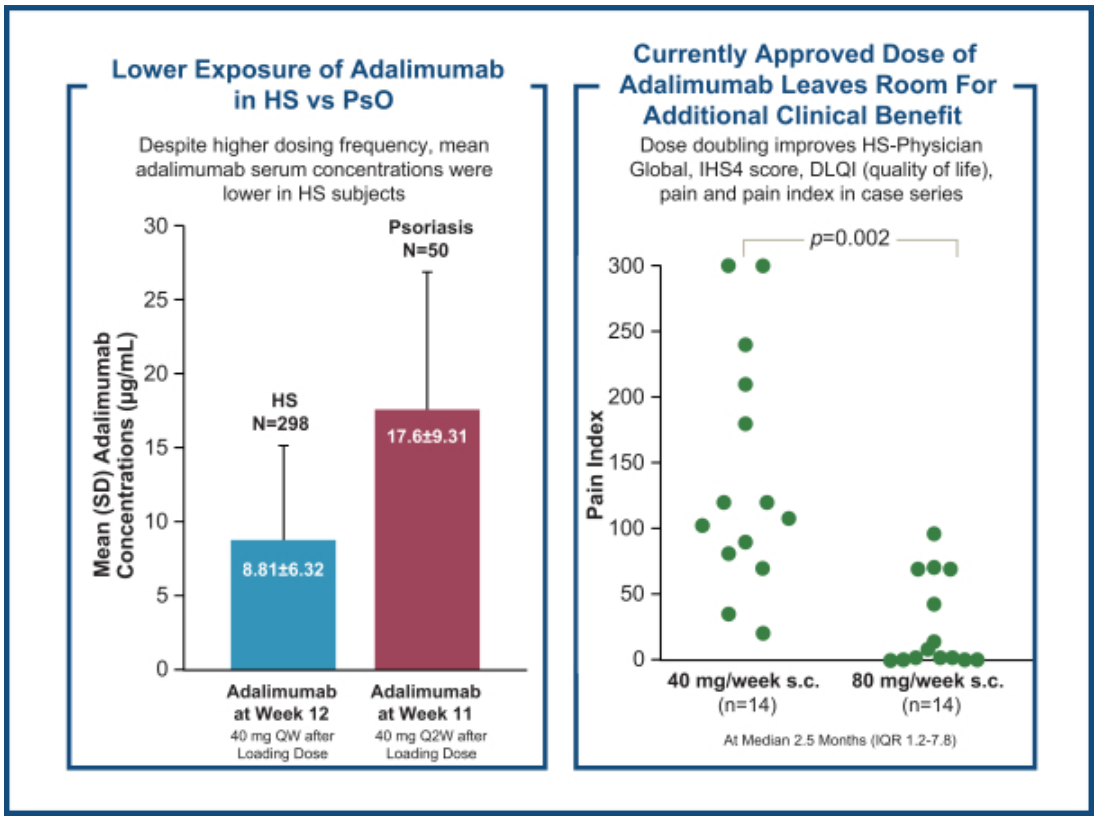


Figure 7. Adalimumab concentrations in HS patients dosed with 40 mg once weekly (QW) were approximately half of that in PsO patients dosed with 40 mg Q2W, despite more frequent dosing in HS. This highlights the need for higher drug exposures in HS, as HS patients treated with adalimumab 80 mg QW had improved efficacy as measured by pain scores with adalimumab dose-doubling.

Our Ongoing Phase 2b/3 Trial of Izokibep in HS

We are currently conducting a Phase 2b/3 trial of izokibep in participants with moderate-to-severe HS.

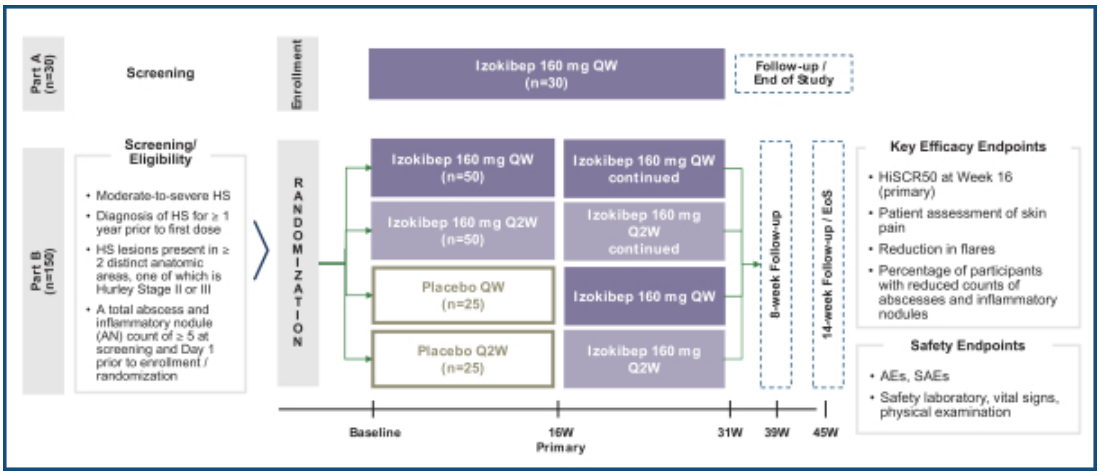


Figure 8. Design of the Phase 2b/3 trial of izokibep in HS.

Part A of this trial is an exploratory open-label, single-arm investigation that enrolled 30 participants dosed with 160 mg izokibep QW. In January 2023, we announced that at Week 12, izokibep achieved higher orders of HiSCR, where low-to-no placebo responses have been reported historically. Safety results were consistent with previous trials of izokibep as well as the anti-IL-17A class as a whole, with no observed increased risk of infection, including candida. Data from Part A of this trial will be presented at a future scientific meeting.

We are currently enrolling a randomized, placebo-controlled double-blind dose-finding Part B of this trial and expect to enroll approximately 150 participants. Participants will be randomized into four cohorts: two cohorts will receive placebo as either a QW or Q2W dosing. Two other cohorts will receive 160 mg izokibep as either QW or Q2W dosing. The primary endpoint will be HiSCR50 at Week 16. Secondary endpoints include the reduction in participants assessment of skin pain, reduction in flares, and percentage of participants with reduced counts of abscesses and inflammatory nodules. After Week 16, participants previously receiving placebo will be dosed with 160 mg izokibep on their previous dosing schedule until the end of the treatment period at Week 32.

An independent interim analysis from this Phase 2b/3 trial, reviewed by a data monitoring committee (DMC), will inform the final dose selection for the planned second Phase 3 trial.

Izokibep for the Treatment of PsA

We are developing izokibep for the treatment of PsA and have initiated enrollment for a Phase 2b/3 trial of izokibep with 160 mg delivered subcutaneously QW or Q2W, or 80 mg once every four weeks (Q4W).

PsA Disease Background

PsA is a chronic immune-mediated inflammatory disease characterized by both joint inflammation and skin lesions consistent with PsO. It is estimated that approximately 30% of the 125 million people living with PsO worldwide will also develop PsA over time. PsA causes pain, stiffness and swelling in and around the joints and commonly appears between the prime productivity ages of 30 and 50, but can develop at any time.

Common symptoms include:

- **Arthritis.** Stiff joints associated with pain and swelling are common signs of arthritis. The arthritis associated with PsA differs from rheumatoid arthritis based on its location in the distal phalangeal joints of the hands and feet, the pelvis and spine.
- **Skin lesions.** Psoriatic lesions caused by inflammation-driven proliferation of skin cells are also found in PsA but the severity of the joint involvement is often worse for patients than the severity of the skin involvement.
- **Enthesitis**. The enthesis is the tissue at the site where a tendon or ligament inserts into the bone. A common site of enthesitis in PsA is the Achilles tendon. Given the forces that pass through the entheseal tissues, they feature high tensile strength and are not very vascular. Inflammation of the enthesis typically causes pain at rest or with movement possibly leading to swelling of surrounding tissues. The pain associated with enthesitis can result in disability and reduced quality of life due to reduced dexterity and mobility. A pooled analysis of two Phase 3 trials found enthesitis to be present in 60-70% of patients with PsA. Enthesitis is believed to be one of the earliest steps in the development of joint inflammation in PsA, which ultimately leads to more serious joint damage. Therefore, early identification of enthesitis and early intervention with an effective treatment could potentially modify the course of a patient's PsA, avoiding the joint erosion, pain and disability associated with more serious disease.

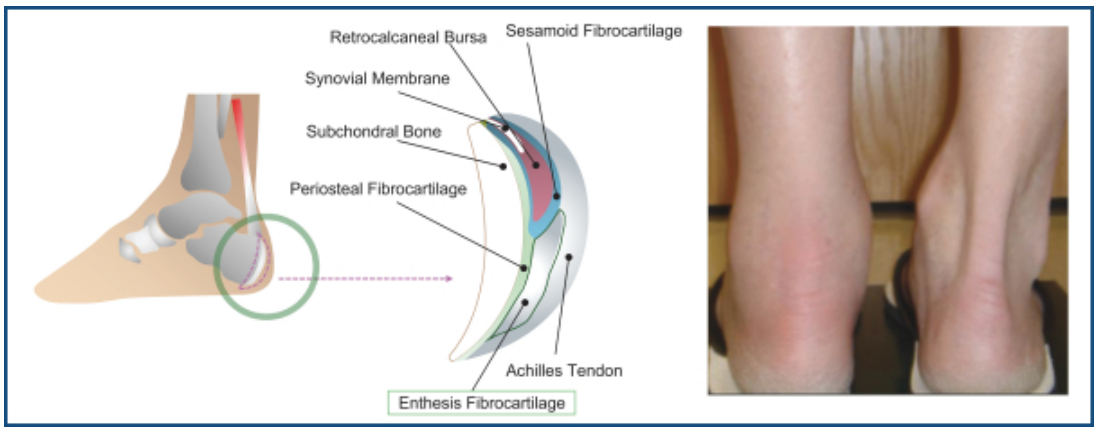


Figure 9. The enthesis is the site of attachment of tendons and bone. Inflammation of the enthesis leads to joint pain and immobility.

- **Dactylitis.** Dactylitis is the uniform swelling of the digits due to inflammation resulting in pain and reduced range of motion. This symptom is commonly referred to as sausage-shaped digits. Dactylitis, which can be very painful, occurs in approximately 50% of patients with moderate-to-severe PsA.
- **Spondylitis.** Spondylitis is a chronic arthritis caused by inflammation of the joints, tendons, and ligaments of the spine and sacroiliac region.

Current Treatments for PsA

Patients with PsA associated with mild arthritis are often first treated with nonsteroidal anti-inflammatory drugs (NSAIDs). As the disease becomes moderate-to-severe, so called "anti-rheumatic" drugs such as methotrexate or leflunomide are added to NSAIDs. Once NSAIDs and/or anti-rheumatic therapies fail, biologic treatment is initiated, with the anti-TNF agent adalimumab amongst the most commonly prescribed biologics. While biologics are needed in PsA, anti-TNF agents or anti-IL-17 agents, such as adalimumab, secukinumab or

ixekizumab are both recommended alternatives. Based on market research conducted for us by Skysis, the total market globally for the treatment of PsA in 2022 was approximately $8.8 billion and is expected to grow to approximately $17.8 billion by 2030.

Despite the availability of these therapies, there is still a large unmet need for more effective therapies to treat PsA across all disease features.

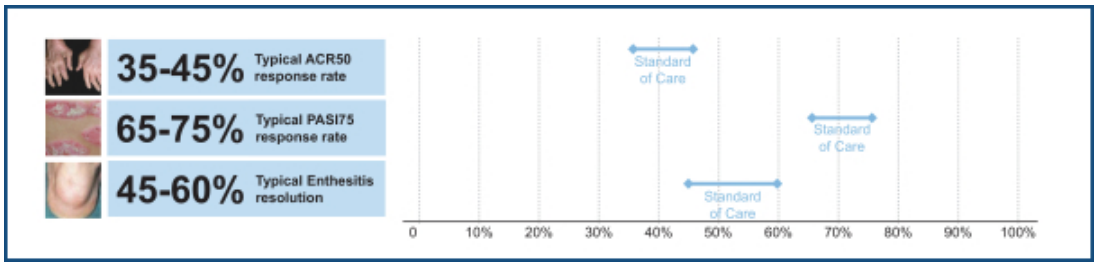


Figure 10. Summary of response rates at Week 16 to 24 for standard of care in PsA.

We have defined standard of care in PsA as shown in Figure 10 to include all approved therapies for treatment of PsA (including adalimumab, ixekizumab, risankizumab, secukinumab, and upadacitinib) and bimekizumab, which is not currently approved for PsA.

PsA is a disease of multiple clinical manifestations, including joint swelling/pain, skin irritation, enthesitis and dactylitis – all contributing to reduced quality of life. There remains significant room for an effective therapeutic that addresses all of these manifestations – and therefore improves quality of life – for these patients.

Summary of the Completed Phase 2 Trial of Izokibep in PsA

We presented results of our placebo-controlled, double-blind Phase 2 trial of izokibep in PsA at the 2022 European Alliance of Associations for Rheumatology (EULAR) Congress and the 2022 American College of Rheumatology (ACR) conference.

The Phase 2 PsA trial enrolled 135 participants across 28 European sites in seven countries. The participant characteristics were similar to those of previous trials in this disease. At Week 16, the placebo cohort was transitioned to 80 mg izokibep and the trial treatment period continued for up to 46 weeks.

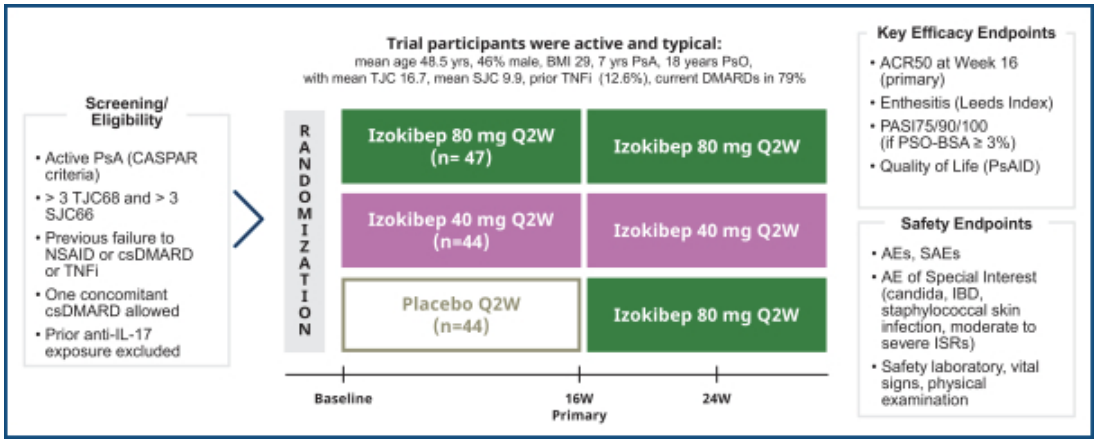


Figure 11. Design of the Phase 2 trial of izokibep in PsA.

We believe the Phase 2 trial results demonstrate izokibep has the potential to provide clinically meaningful, differentiated benefits in the treatment of PsA over existing therapies.

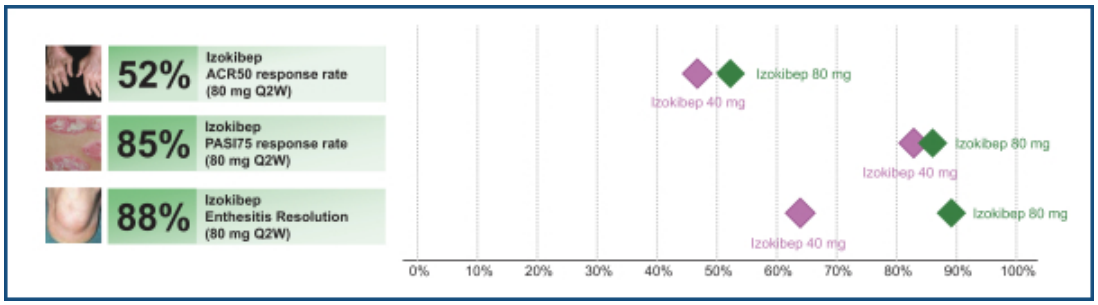


Figure 12. Key results of the Phase 2 trial of izokibep in PsA at Week 16.

In the trial, both doses of izokibep demonstrated significant improvements compared to placebo. Results for the 80 mg dose in particular exceeded the joint and psoriasis responses of approved therapies utilized to treat moderate-to-severe PsA, and resolution of enthesitis was markedly differentiated from historically reported response rates.

In addition to joints, skin and enthesitis, dactylitis and nail PsO are additional difficult-to-treat manifestations of PsA. Using the Leeds Dactylitis Index-B, we observed that more than 65% of participants had complete resolution of their dactylitis whereas only 27% of placebo participants had resolution at 16 weeks, with a placebo corrected difference of >35% for both izokibep doses. This is at the high end of dactylitis complete resolution rates and consistent with the best observed rates for secukinumab, ixekizumab, and upadacitinib on an absolute and placebo corrected basis.

Participant-Reported Outcomes

Our ultimate goal is to improve quality of life for the patients. To that end, we assessed multiple measures of participant-reported outcomes as part of the trial, including the Psoriatic Arthritis Impact of Disease (PsAID) questionnaire developed and validated by GRAPPA (the Group for Research and Assessment for PsA), a preeminent group of rheumatology thought-leaders.

The PsAID results for the overall trial population in this trial revealed statistically significant, clinically meaningful and dose-dependent improvements in all quality of life sub-domains of the PsAID, including pain, sleep disturbance and functional capacity. Furthermore, we observed the participants with enthesitis at baseline reported even greater improvement in quality of life.

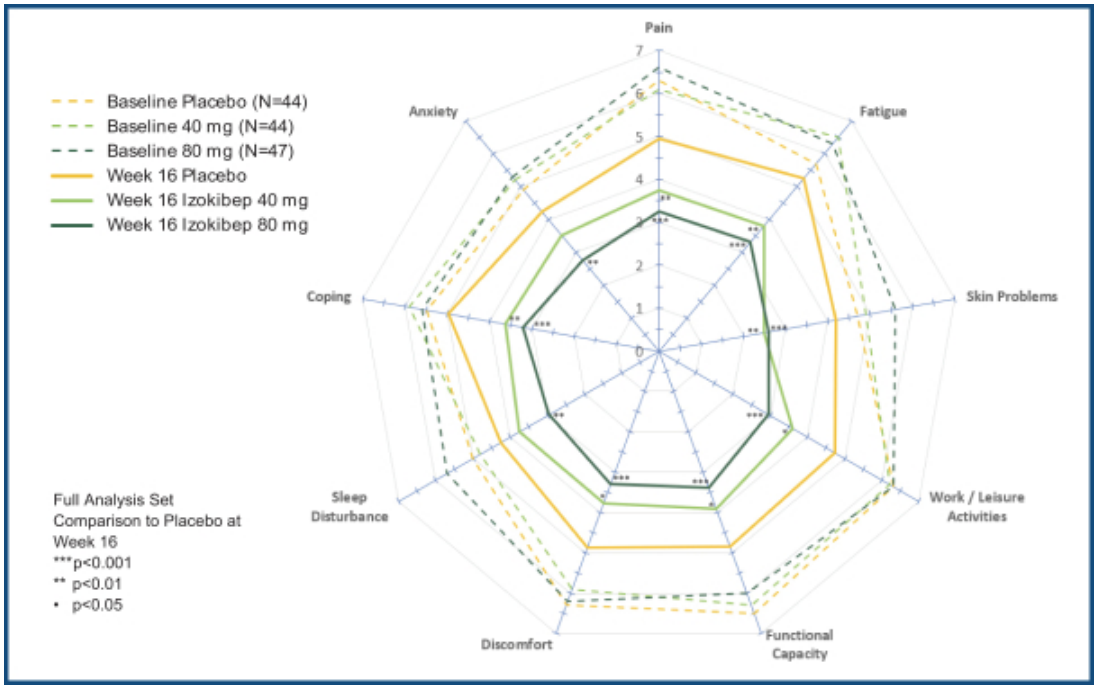


Figure 13. Izokibep led to a dose-dependent response across the spectrum of participant reported outcomes as measured by PsAID. In this radar plot; lower scores closer to the center of the figure represent better outcomes. Each spoke represents a participant reported outcome from the PsAID. Changes in the magnitude of the scores of individual outcomes are represented by the distance from the center point.

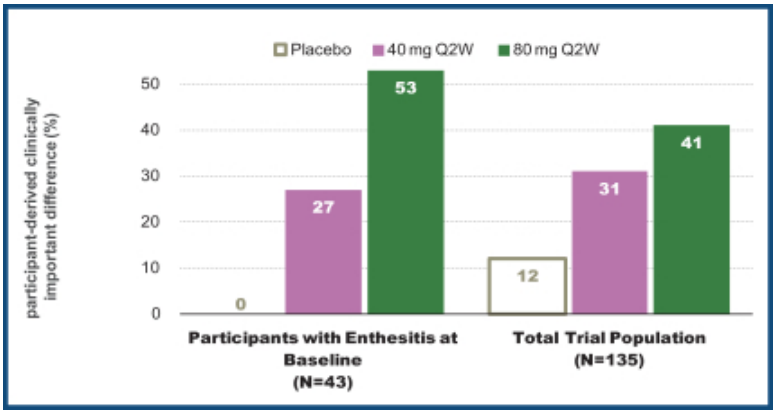


Figure 14. Participants with enthesitis at baseline reported a higher percentage of clinically meaningful improvements in PsAID with izokibep compared to the overall trial results.

Safety Profile

In this Phase 2 trial, izokibep was well-tolerated – in line with previous trials of izokibep and the IL-17A class as whole – and no treatment-related serious adverse events (SAEs) were reported/observed across all cohorts. The most common adverse event (AE) was injection site reactions. Injection site reactions were mild-to-moderate, the size of a quarter to half dollar, and typically presented within the first three injections, after which they generally did not occur.

Pharmacokinetic-Pharmacodynamic (PK-PD) Modeling Supports Higher Doses

Based on the lack of plateau in clinical response in the Phase 2 trial in PsA and lack of dose-related safety concerns, modeling was performed to determine the potential for additional clinical response with higher dosing.

In our exposure modeling, the 160 mg QW dose of izokibep led to a seven-fold increase in the minimum serum concentration (C_{min}) and the 160 mg Q2W dose led to a two-fold increase in C_{min} both compared to 80 mg Q2W. In general, higher C_{min}, or trough circulating drug concentrations, is an important determinant of disease control for chronic inflammatory illnesses.

As demonstrated in Figure 15 below, using industry standard computational PK-PD modeling, we estimated the higher 160 mg Q2W and 160 mg QW doses resulted in a projected approximately 10% increase in ACR50 as well as PASI100 responses at Week 16, and predicted a further approximate 10% benefit with longer treatment duration over 46 weeks. Similarly modeled data also predicted improved enthesitis resolution at these doses as well as over time.

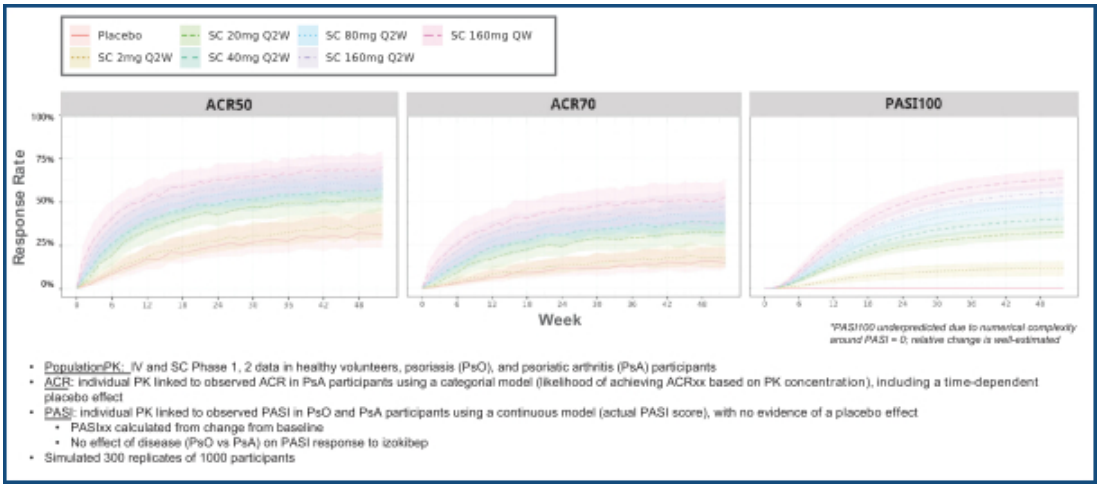


Figure 15. Modeled up to 48-week data predicted consistent evidence of additional exposure response across clinically validated PsA endpoints.

Pre-existing antibodies and treatment emergent anti-drug antibodies (ADAs) were detected in participants treated with izokibep in Phase 1 and Phase 2 trials. However, there was no observed correlation between the presence of these antibodies and drug exposures, clinical improvements on standard outcome measures or adverse events.

Among the more than 400 participants treated with izokibep to date, more than 100 participants have been treated with the 160 mg dose. We have not observed an increase in the incidence of adverse events at this higher dose level compared to lower dose levels, and the 160 mg dose level has been generally well-tolerated.

Ongoing Phase 2b/3 Trial in PsA

We have initiated in the United States, Europe, and Canada a placebo-controlled, double-blind Phase 2b/3 trial of izokibep in PsA. We intend to enroll approximately 325 participants and investigate 160 mg doses QW, 160 mg doses Q2W and 80 mg Q4W. The design of this trial is similar to that of the Phase 2 trial: after 16 weeks, participants on placebo will receive izokibep for the remainder of the 52-week trial period. Similar to our completed Phase 2 trial, the primary endpoint of this Phase 2b/3 trial is the commonly accepted regulatory endpoint of ACR50 at Week 16 and key secondary endpoints include PASI90, enthesitis resolution rates and participant reported quality of life. Efficacy and safety will continue to be evaluated up to 52 weeks.

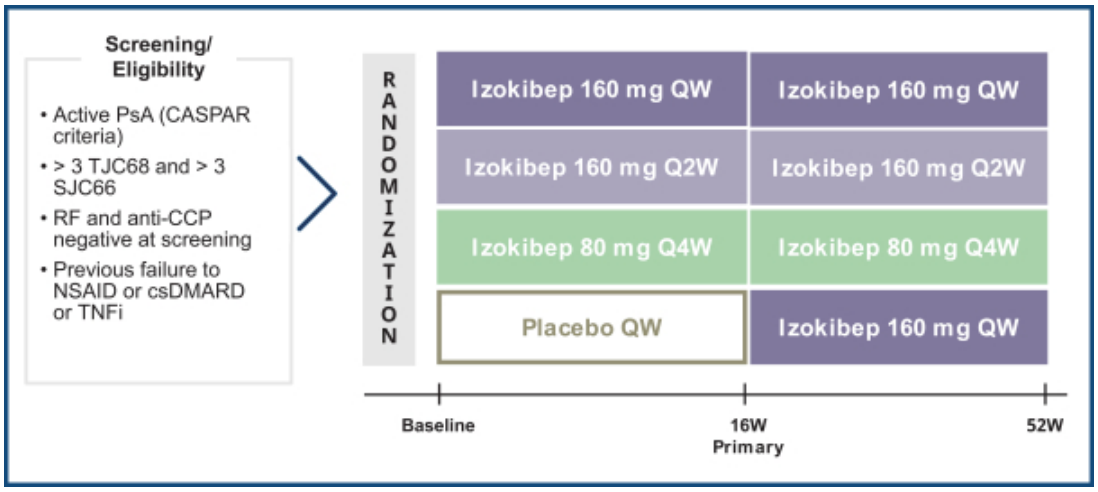


Figure 16. Design of the Phase 2b/3 trial of izokibep in PsA.

We anticipate at least one additional Phase 3 trial will also be required for approval in PSA.

Izokibep for the Treatment of AxSpA

AxSpA is a chronic inflammatory disease predominantly affecting the axial skeleton, primarily the spine from the pelvis to the neck, although it often affects peripheral joints including knees, hips, and shoulders. The most common symptom is persistent pain in the lower back, buttocks and hips. Over time the joints and bones in the spine and rib cage may fuse together making movement and chest expansion difficult.

Approximately 60-70% of patients with AxSpA have peripheral arthritis and peripheral enthesitis. Enthesitis is inflammation of the enthesis where the tendons and ligaments attach to bone. In AxSpA, everywhere that the anterior and posterior longitudinal ligament attaches to the vertebral body of the spine is through an enthesite. As such, enthesitis is central to the disease pathology of AxSpA and is known to be the key initiating event for AxSpA, with inflammation on the enthesite seen on x-ray and known as the "Romulus lesion," the earliest form of AxSpA seen on x-rays of the spine.

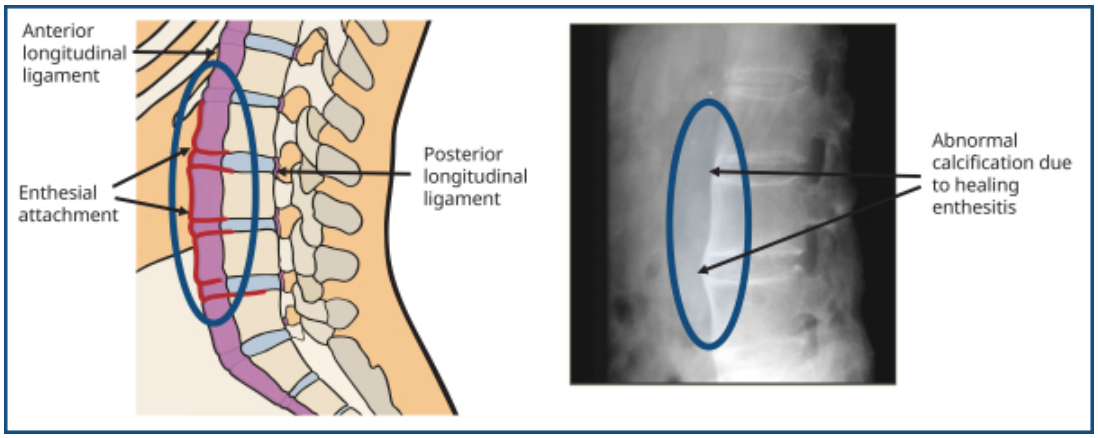


Figure 17. Illustration and radiograph of AxSpA with abnormal calcification due to healing enthesitis evident along the anterior longitudinal ligament.

The treatment approaches for AxSpA are similar to PsA. NSAIDs are first line treatment of early-stage disease, with biologics such as anti-TNF and anti-IL-17 monoclonal antibodies indicated for patients failing NSAIDs. Response rates in AxSpA are measured using the Assessment of SpondyloArthritis International Society (ASAS) response criteria, a clinically validated scoring system that captures meaningful changes in spinal pain, patient global assessment, pain function and inflammation. The ASAS40 response rates represent a 40% improvement from baseline. In randomized double-blind Phase 3 trials evaluating secukinumab and ixekizumab, 30% and 50% of patients, respectively, reached the 40% improvement threshold, with both agents demonstrating statistically significant improvements on ASAS40 compared to placebo.

There are an estimated 2.5 million patients with AxSpA in the United States and Europe, with 150,000 of such patients currently treated with biologics. Based on market research conducted for us by Skysis, the total market globally for the treatment of AxSpA in 2022 was approximately $5.1 billion and is expected to grow to greater than $6.8 billion by 2030.

Enthesitis is central to the pathology of AxSpA and the enthesitis resolution rates observed in our Phase 2 trial of izokibep in PsA have strengthened our hypothesis for our AxSpA program. Each location that the anterior and posterior ligaments attach to a vertebral body of the spine is through an enthesite. Enthesitis in the vertebral spine has been shown in MRI studies to be the earliest inflammatory event in AxSpA.

Once the optimal dose is selected in PsA, we intend to initiate two Phase 3 double-blind, placebo-controlled trials in AxSpA with that chosen dose. We expect to conduct one trial in both radiographic and non-radiographic AxSpA, each with a ASAS40 at 16-week primary endpoint. After 16 weeks, placebo participants will switch to active therapy and the trial will continue to 52 weeks.

Izokibep for the Treatment of Uveitis

We are currently conducting a Phase 2b/3 trial of izokibep in non-infectious uveitis.

Uveitis is an inflammatory disease of the eye that sometimes arises in association with other immune-related diseases. More than 90% of uveitis cases have been reported to be non-infectious, chronic and recurrent in nature with a prevalence in the United States of 121 cases per 100,000.

Patients affected by uveitis are at risk of permanent visual impairment. Cystoid macular edema was identified as the leading cause of visual impairment and blindness in patients with uveitis although disease complications of cataracts and glaucoma can also threaten vision. Although all anatomical sites of inflammation associated with uveitis have the potential to lead to visual impairment and blindness, the risk is highest in patients with non-anterior uveitis. A loss of visual acuity (25% or greater) occurs in 66% of patients with intermediate uveitis, 43% of patients with posterior uveitis and 40% of patients with panuveitis.

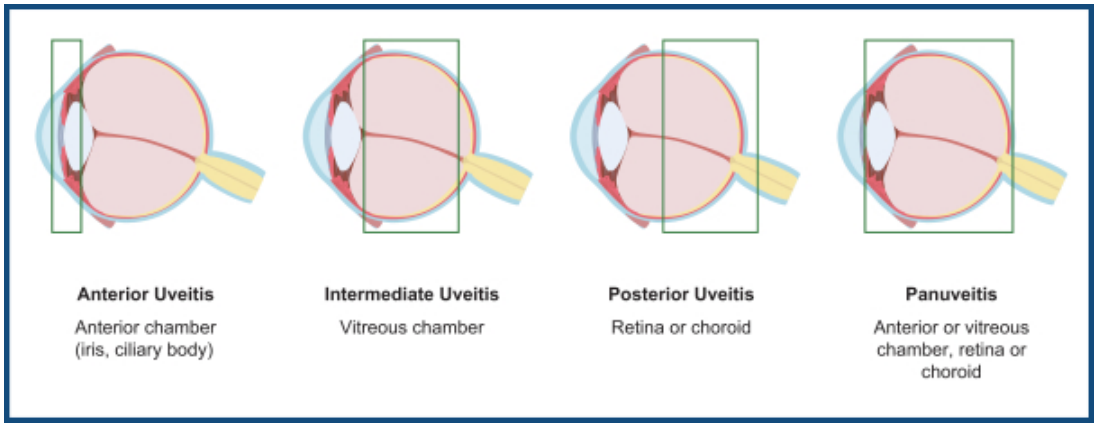


Figure 18. Uveitis is characterized by the anatomical location of the primary inflammation. Only anterior uveitis is typically treatable with topical glucocorticoids.

Treatment options and prognoses are dependent on the anatomical location of symptoms. Non-anterior inflammation – behind the lens – often requires systemic treatments as therapies administered to the surface of the eye do not pass beyond the lens; non-anterior uveitis is most commonly autoimmune. Glucocorticoids are used for short-term control of inflammation, and in lower doses are used longer term. However, glucocorticoids are associated with systemic toxicity such as hypertension, diabetes, infections and osteoporosis. They also cause toxicity to the eye including glaucoma and cataracts. Ophthalmologists may try other agents such as methotrexate and mycophenolate to control inflammation and reduce the dose of glucocorticoids.

Adalimumab is the only approved therapy for patients with non-infectious, non-anterior uveitis who have persistent active inflammation and is indicated for all patients in this setting.

Our market research suggests that there are 60,000 patients with non-infectious, non-anterior uveitis in the United States and an aggregate of 50,000 patients in France, Germany, Spain and the United Kingdom. Adalimumab, the only approved biologic for these patients, provides only temporary benefits for many patients; relapse/failure is observed in 39% to 55% of patients within a year with a mean time to relapse/failure of 5.6 months. Based on market research conducted for us by Skysis, the total market globally for the treatment of non-infectious uveitis was approximately $390 million in 2022 and is expected to grow to greater than $790 million by 2030.

Evidence for the Role of IL-17A Inhibitors in the Treatment of Non-infectious Uveitis

Uveitis is thought to be driven by autoreactive T cells targeting ocular tissues and acting in concert with cells of the innate immune system. Circulating levels of Th17 cells, producers of IL-17A, are elevated during active uveitis and reduced following effective treatment.

A previous Novartis trial from 2017 demonstrated the clinical benefits of targeting IL-17A with secukinumab in uveitis, although higher exposures delivered by IV infusion were required.

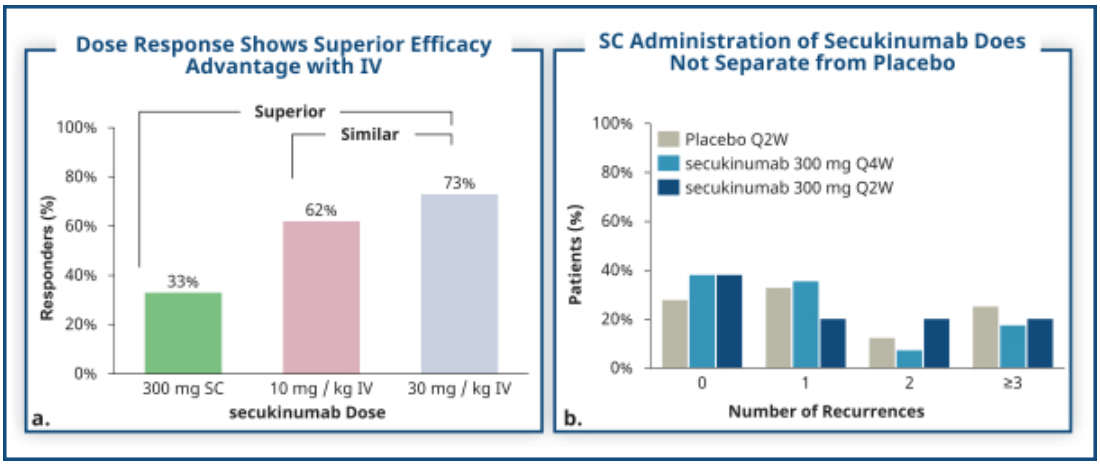


Figure 19. (a) IV dosing of secukinumab increased the response rate in uveitis compared to 300 mg secukinumab administered subcutaneously and (b) subcutaneous doses of 300 mg secukinumab did not meet the primary endpoint of reduction in occurrence of uveitis.

The importance of adequate exposures was demonstrated in a dose-ranging trial in 37 patients with non-infectious uveitis, where secukinumab was administered as a 300 mg subcutaneous injection every two weeks, a 10 mg/kg IV infusion every two weeks or a 30 mg/kg IV infusion every four weeks. The administration of secukinumab by IV infusion resulted in higher drug exposures and statistically significant improved response rates as compared to the 300 mg subcutaneous injection. Administration of higher doses of secukinumab subcutaneously is limited by the ability to only deliver 150 mg for each 1 ml injection and achieving drug exposures similar to 10 mg/kg IV would require 6-8 subcutaneous injections every two weeks.

We are not aware of any further registrational trials of secukinumab for this indication, potentially due to the challenges of IV delivery in the ophthalmology setting. We believe that izokibep has the potential to deliver meaningful clinical responses in uveitis as a result of its ability to deliver more potent IL-17A inhibition through subcutaneous injections. Even if further IV-administered therapies were developed, we would expect ongoing delivery challenges as ophthalmology practices are not typically equipped to deliver IV therapies.

In addition, since izokibep delivers subcutaneous exposures with 160 mg QW that approximate those seen with IV secukinumab 10 mg/kg, izokibep exposures approximate those known to be effective with secukinumab and the IL-17A pathway. Given that secukinumab is available currently as a 150 mg autoinjector, to achieve the exposures seen with 10 mg/kg IV would require approximately 6-8 subcutaneous injections of secukinumab every two weeks.

Furthermore, izokibep has been shown in preclinical cynomolgus monkey studies to gain access to the posterior eye, where non-anterior, intermediate-, posterior- or pan-uveitis occurs, in a manner that is proportional to serum levels.

Ongoing Phase 2b/3 Trial in Uveitis

We have initiated a Phase 2b/3 multi-center, randomized, double-blind, placebo-controlled dose-finding trial in uveitis in North America and Europe.

The aim of the trial is to investigate the efficacy, safety and immunogenicity of izokibep in participants with active non-infectious, intermediate-, posterior- or pan-uveitis in at least one eye. All participants will commence 60 mg of prednisone or equivalent at baseline, to be tapered off by Week 15. We anticipate enrolling approximately 120 participants. The trial consists of up to a 28-day screening period, a 51-week treatment period and a follow-up visits at eight weeks and 14 weeks to assess safety and immunogenicity. Eligible participants will be randomized into one of four groups as shown in Figure 20 below:

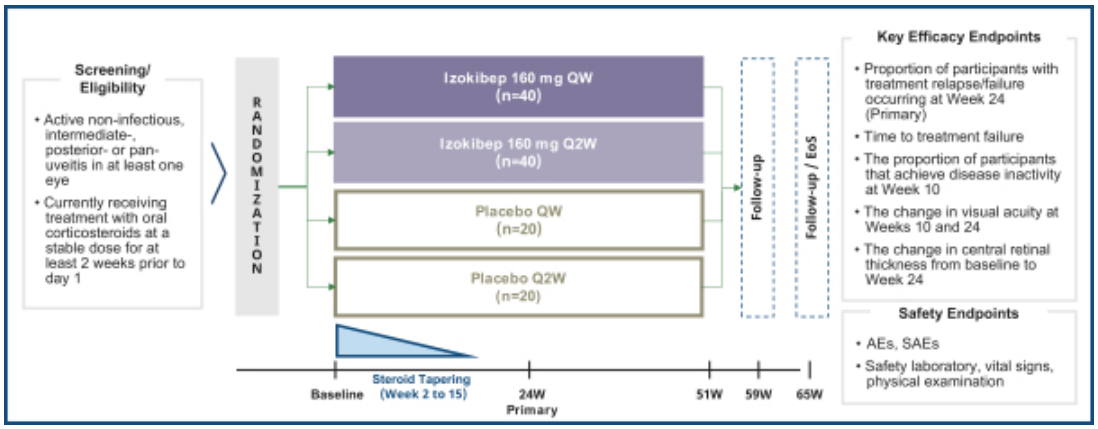


Figure 20. Design of the Phase 2b/3 trial of izokibep in uveitis.

The trial primary endpoint is the proportion of participants with treatment relapse/failure occurring at Week 24. Secondary endpoints are time to treatment failure, the proportion of participants that achieve disease inactivity at Week 10, the change in visual acuity at Weeks 10 and 24 and the change in central retinal thickness from baseline to Week 24.

Safety Profile of Izokibep

Izokibep has been administered to more than 400 participants, including at doses up to 160 mg and in some for up to three years. Izokibep has generally been well-tolerated with a safety profile consistent with that of the anti-IL-17A class as a whole. In our completed trials the most common adverse event (AE) we observed was injection site reactions which include redness, pain and swelling at the injection site.

Injection site reactions were mild-to-moderate, the size of a quarter to half dollar, and typically presented within the first three injections, after which they generally did not occur. If needed, symptoms were generally managed with ice or topical over-the-counter cortisone cream. We observed trial participant discontinuation rates of approximately 1-2% due to injection site reactions, consistent with anti-IL-17A approved therapies.

The following safety summary is derived from the most recent investigator's brochure, which was published in July 2022, as well as Week 16 data from our completed Phase 2 trial in PsA, which were presented at EULAR in June 2022.

Table 1: Safety summary—Phase 1 and Phase 2 PsO trials and Week 16 Phase 2 PsA trial

Study	Current Status (January 2023)	Deaths	SAE(1)	AEs >5%(2)(3)
Phase 1 trial in healthy volunteers (n=46) and PsO (n=26)	Completed	No deaths	1 SAE in PsO subject. Not related to study treatment.	Most common AEs were mild-to-moderate: injection site reactions (n=13/21)(4) headache (n=14/62) nasopharyngitis (n=12/62) contusion (n=7/62) arthralgia (n=6/62) oropharyngeal pain (n=6/62)
Phase 2 trial in moderate-to-severe PsO (n=108)	Completed the 52- week core study period; year 2 and 3 extension periods ongoing	No deaths	15 SAEs in 10 subjects reported. None were related to study treatment	Most common AEs were mild-to-moderate:(5) injection site reactions (n=29/86) nasopharyngitis (n=19/86) diarrhea (n=10/86) headache (n=9/86) fatigue (n=6/86)
Phase 2 trial in moderate-to-severe PsA (n=135)	Week 16 primary data available; week 46 study data pending	No deaths	No SAEs reported up to 16 weeks.	Most common AEs were mild-to-moderate: injection site reactions (n=37/91) upper respiratory tract infection (n=5/91)

(1) Relatedness to study treatment as determined by study investigator.
(2) Measurement of injection site reaction in Phase 1 PsO trial was based on patient self-reporting on a questionnaire specifically querying injection site reactions, compared to spontaneous reporting in the Phase 2 trials in PsO and PsA. Measurement of all other AEs was based on spontaneous reporting.
(3) Excludes placebo.
(4) Only represents subcutaneous administration cohorts.
(5) Measured over the 12-week placebo-controlled period.

Our Lonigutamab (IGF-1R Monoclonal Antibody) Program

Summary Overview of Lonigutamab

Lonigutamab, our second development program, is a subcutaneously delivered humanized IgG1 monoclonal antibody against IGF-1R for the treatment of TED. Lonigutamab was acquired in our January 2023 acquisition of ValenzaBio. We currently hold exclusive worldwide development and commercialization rights to lonigutamab outside of oncology, which are held by Pierre Fabre.

Lonigutamab targets a distinct epitope of IGF-1R and has *in vitro* potency up to 75-fold higher than that of teprotumumab. Our preclinical studies demonstrated that, when biopsy samples from TED participants were treated with equimolar amounts of teprotumumab and lonigutamab, lonigutamab had greater inhibition of IGF-1R signaling as measured by hyaluronan production. Furthermore, we believe that the characteristics of lonigutamab that enable subcutaneous delivery also allow for reduction of maximum serum concentration (C_{max}) incurred with current IV therapies. Decreasing C_{max} may lessen breach of the blood labyrinth barrier and limit IGF-1R inhibition in the neural tissues of the inner ear. IGF-1R is neuroprotective to cells of the inner ear and serves to repair the cellular damage that occurs by various processes including age-associated degeneration. In addition to the potential benefit of decreasing the side effect of hearing impairment, these characteristics of lonigutamab enable evaluation for greater depth and durability of clinical response. The MAD portion of our Phase 1 trial in TED is currently recruiting.

Thyroid Eye Disease (TED) Overview

TED is a potentially vision-threatening progressive autoimmune ocular disease in which the eye muscles, eyelids, tear glands and fatty tissues behind the eye become inflamed. Although the inflammatory process appears to wax and wane clinically, recurrent inflammation, scarring and fibrosis lead to pathological changes in the tissues surrounding the eyeball. Initial TED symptoms include redness, irritation, and discomfort of the eyes and eyelids, pain and headaches. As the fat and muscle tissues surrounding the eye continue to swell, disabling symptoms include double vision and corneal erosions due to eye bulging and the subsequent inability to close the eyelids. Elevated ocular pressure can occur with compression of the retinal nerve, leading to blindness (optic neuropathy). The most obvious feature of TED is the protrusion of the eye outward from the eye socket (proptosis).

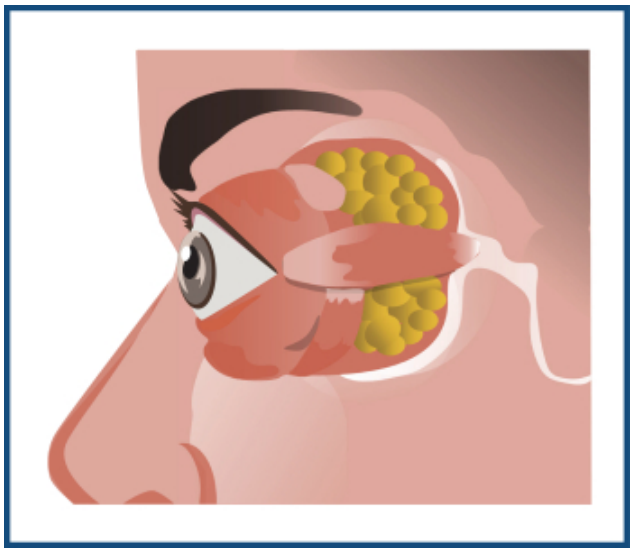


Figure 21. Illustration of TED.

The incidence of TED in the United States has been estimated to be approximately 16 per 100,000 females and 3 per 100,000 males. Cigarette smokers appear to have an increased risk of developing TED and when they do, often have more severe and prolonged activity that threatens vision. It's estimated there are more than 100,000 chronic TED patients in the United States, with more than 20,000 moderate-to-severe patients suffering high degrees of eye bulging (proptosis) and double vision (diplopia). Its further estimated that there are more than 80,000 moderate-to-severe patients with high degrees of proptosis and/or diplopia with low clinical activity. Based on market research conducted for us by Skysis, the total market globally for the treatment of TED in 2022 was approximately $2 billion and is expected to grow to more than $4.8 billion by 2030.

Pathogenesis of TED

TED is caused by the activation of the patient's immune cells and the production of pathological autoantibodies that attack tissues around the eye. About 90% of TED patients have an autoimmune disease called Graves' disease or Graves ophthalmopathy leading to the development of hyperthyroidism. Graves' disease is associated with activation of fibroblasts in the orbital area surrounding the eye promoting inflammation and scarring of tissues around the eye.

Fibroblasts are activated through a receptor known as IGF-1R. IGF-1R results in increased production of proinflammatory cytokines and hyaluronan which causes tissue swelling and leads to the disease features described above. IGF-1R is a ubiquitously expressed receptor involved in the regulation of proliferation and metabolic function of many cell types. Inhibition of IGF-1R by teprotumumab (marketed as Tepezza) has been clinically validated to reduce the symptoms and leads to disease modification of the more severe disease features, such as bulging and double vision, of TED.

Current Treatments for TED

Patients with mild TED and the absence of proptosis are often treated with local agents, such as lubricants or ointments and advised to focus on reducing irritants, such as those from cigarette smoke, and use dark glasses to reduce bright light exposure.

More severe disease has been generally treated with off-label glucocorticoids, often administered by weekly IV infusion. Glucocorticoid treatment may reduce active inflammation but chronic glucocorticoid use is associated with serious complications including high blood pressure, diabetes, psychological effects, osteoporosis, and increased risks of infections. None of the foregoing treatments are disease modifying in contrast to IGF-1R inhibition, which is disease modifying as demonstrated by teprotumumab. Teprotumumab, the only FDA-approved treatment for TED, is an IGF-1R monoclonal antibody that has led to significant improvements across multiple disease features including proptosis, diplopia, strabismus, inflammation and reduction of orbital soft tissue volume. Teprotumumab was granted Orphan Drug Designation for TED.

For individuals who have inadequate disease control, including with teprotumumab, surgery is the only remaining option. Surgery is difficult and risky because a limited amount of bone and muscle tissue can be safely removed from the area around the eye.

Limitations of Currently Approved Therapy

Despite recent development of new standards of care that have led to disease modification and greatly improved the quality of life for patients with TED, there remains opportunities for improved efficacy and safety, all facilitated through more convenient subcutaneous dosing.

Durability/Relapse/Depth of Response

The current standard of care is delivered via IV dosing and the prescribing information recommends a total of 8 infusions given every three weeks, for a total of 24-week treatment. As a chronic inflammatory illness, 24 weeks of treatment for TED may be insufficient for some patients due to lack of complete resolution of disease signs and symptoms. It has been reported that approximately 37% of teprotumumab trial participants who initially responded at the end of treatment at Week 24, suffered a relapse in proptosis by Week 72, highlighting the clinical need for more durable responses and the avoidance of disease relapse.

Hearing Impairment

Approximately 10% of participants in Phase 2 and Phase 3 trials for teprotumumab reported developing hearing impairment symptoms. These symptoms included subjective hearing loss, tinnitus, an ear plugging sensation or muffled hearing and autophony, or abnormal hearing of one's own voice.

This concerning side effect may be directly related to targeting of IGF-1R, which is understood to participate in neuroprotective activities where it maintains cellular metabolism, activates growth, proliferation and differentiation, and limits cell death. These functions serve to repair cellular damage in the ear that occurs by various processes including age-associated degeneration. Highlighting the impact of this side effect of targeting IGF-1R, a study conducted by Stanford University following 28 participants receiving teprotumumab suggests that the rate of developing hearing symptoms may be much higher in real world settings than reported in the clinical trials, potentially exceeding 45%. Multiple case studies following individual patients have also shown that hearing impairment may be prolonged, with no improvement in symptoms even months after cessation of treatment.

Hyperglycemia

Another common side effect of teprotumumab treatment is hyperglycemia, or increased blood glucose, which was reported in approximately 10% of participants in the Phase 2 and 3 trials. Hyperglycemia is particularly important to manage in patients with TED, as many also have pre-existing diabetes or impaired glucose tolerance with two thirds of participants in the Phase 2 and 3 trials experiencing hyperglycemia also having pre-existing diabetes or impaired glucose tolerance.

We believe that this hyperglycemia may result from unintended inhibition of the insulin receptor, which is structurally similar to IGF-1R. This structural similarity serves to make the insulin receptor potentially a direct target of IGF-1R antibodies and renders the insulin receptor sensitive to inhibition along with IGF-1R through the formation of heterodimers, or linked pairs of insulin receptor and IGF-1R.

IV Infusion

The need for IV infusions of teprotumumab in a medical facility requires complicated coordination between the patient and the facility. An IV infusion of teprotumumab initially takes 90 minutes, which can potentially be reduced to 60 minutes over time if well tolerated. Patients must be further monitored after the infusion, as adverse reactions can occur up to 90 minutes following the infusion. As such, each infusion visit could potentially require three to four hours in the medical facility, in addition to travel time.

Our Solution: Lonigutamab

Lonigutamab is a humanized IgG1 monoclonal antibody against IGF-1R with an *in vitro* potency, as measured by K_D of less than 0.03 nM, which is up to 75-fold higher than that of teprotumumab. Lonigutamab achieves a higher potency through the targeting of a distinct epitope on IGF-1R.

Furthermore, targeting the needed C_{min} from the start and allowing for treatment beyond 6 months could facilitate a potential for improved depth and duration of response, as described above. While teprotumumab dosing requires 3-5 doses to achieve optimal C_{min} levels, lonigutamab may achieve these C_{min} levels with the first dose, with the potential to better control disease earlier. More complete control throughout the disease course is possible with chronic dosing beyond six months, facilitated through the potential for at home subcutaneous injections. Our objective is to treat patients individually to complete resolution of signs and symptoms, in a personalized approach.

Reducing the C_{max} seen with current IV therapies via a subcutaneous route of delivery may lessen the breach of the blood labyrinth barrier and enable lesser IGF-1 inhibition in the neural tissues of the inner ear while still achieving clinically meaningful, differentiated patient outcomes.

We also believe that two properties of lonigutamab may help reduce the 10% rate of hyperglycemia seen in clinical trials of teprotumumab. First, lonigutamab binds to a distinct epitope on IGF-1R, with lower affinity to the insulin receptor *in vitro*. Second, lonigutamab binding to IGF-1R leads to faster receptor internalization than teprotumumab, as internalization was measured and detected at meaningful levels in minutes *in vitro* for lonigutamab, relative to lower levels in hours or days. We hypothesize this rapid internalization of homodimer IGF-1R with lonigutamab lowers the potential for the reduction of heterodimers between IGF-1R and the insulin receptor and may help reduce the risk of hyperglycemia.

An enhanced safety profile, with comparable or better clinical outcomes, relative to the standard of care could also open up the possibility of treating patients with earlier stage disease, rather than waiting for the more severe disease features of eye bulging and double vision to reach their peak.

Finally, the potential to deliver lonigutamab via subcutaneous injection at targeted therapeutic doses has been demonstrated by the SAD portion of our ongoing Phase 1 clinical trial. This route of administration could allow for improved clinical outcomes and convenience. Furthermore, subcutaneous self-injection could facilitate the treatment of TED patients beyond the surgery setting, for example in ophthalmologists' and endocrinologists' offices where TED patients are also seen and treated.

Clinical Development

The SAD portion of this trial included 64 healthy volunteers, and was designed to assess the PK and tolerability of lonigutamab and confirm the potential to administer lonigutamab subcutaneously. Data from the SAD portion of the ongoing Phase 1 trial will be presented at the 2023 North American Neuro-Ophthalmology Society meeting.

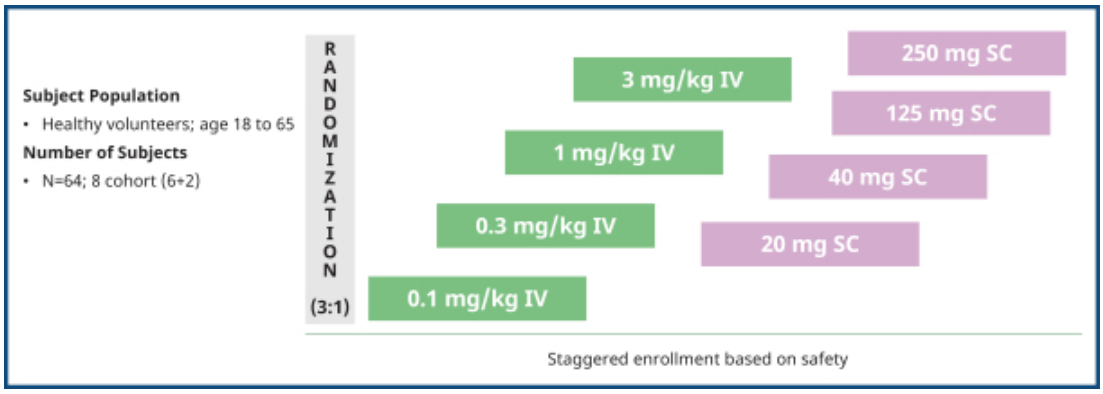


Figure 22. Design of the SAD portion of the Phase 1 trial of lonigutamab.

The MAD portion of our ongoing Phase 1 trial in TED is currently open and recruiting, and is designed to generate early proof-of-concept data.

Our XLRN-517 (c-KIT Monoclonal Antibody) Program

We are also developing XLRN-517, a fully human monoclonal antibody designed to target a distinct epitope of c-KIT, the inhibition of which can reduce mast cell proliferation and activity in various allergy and inflammatory diseases. XLRN-517 aims to address the root cause of mast cell-driven diseases by blocking mast cell proliferation and reducing the degranulation of mast cells, limiting their toxic cellular products from being released into the circulation.

Mast cells appear to play a central role in various allergic and inflammatory diseases. XLRN-517 is a fully human IgG1 monoclonal antibody with highly potent inhibition (antagonism) of the c-KIT pathway, targeting mast cell proliferation and degranulation, without stimulation (agonism) of mast cell degranulation. XLRN-517 has lower potential for immunogenicity relative to monoclonal antibodies that are not fully human. These features have the potential to block mast cell growth without inadvertently triggering degranulation. XLRN-517's picomolar binding affinity and the high *in vitro* potency observed from cell-based functional assays suggest that low volume subcutaneous dosing is feasible in the clinic.

Binding Affinity, SPR (KD)	2.8pM
Inhibition of SCF Mediated Mast Cell Proliferation (IC50)	400pM
Inhibition of IgE Dependent Degranulation (IC50)	54pM
Projected Human Dose	<1mg/kg

Figure 23. Key characteristics of XLRN-517.

Our first indication of interest for XLRN-517 is chronic urticaria, commonly known as chronic hives, an inflammatory disease that is driven by the release of histamine and other vasoactive molecules by mast cells. c-KIT serves as a master regulator of mast cell activity and has been validated as a target that can inhibit mast cell activation in patients with chronic urticaria. Based on market research conducted for us by Skysis, the total market globally for the treatment of chronic urticaria in 2022 was approximately $1.9 billion and is expected to grow to approximately $5.8 billion by 2030.

XLRN-517 has higher affinity and is more potent across a number of *in vitro* assays than other antibodies targeting this pathway. Furthermore, we believe XLRN-517 has the potential to address multiple indications beyond chronic urticaria, in diseases where mast cells appear to be a key part of the pathogenesis. Other potential indications where mast cells may play a central role include prurigo nodularis, bullous pemphigoid, and eosinophilic esophagitis.

A Late-Stage Clinical Biopharma Company Creating an Industry Leading Portfolio

We are an experienced management team with a track record of delivering the first approvals, or expanded indications, for transformative therapies. We have secured more than $550 million in committed capital since our founding in 2020, of which over $400 million has already been funded and $150 million will be funded, subject to certain conditions, by our Series C preferred stock investors if this offering is not completed by June 30, 2023, and have utilized those funds to build an industry-leading immunology pipeline.

Our lead product candidate is izokibep, a pipeline in a program. We hypothesized that high potency and small size would lead to clinically meaningful, differentiated impact for patients. Recent Phase 2 data in HS and PsA support this hypothesis with two independent data sets. Furthermore, we believe both lonigutamab and XLRN-517 have similar potential to improve upon the current standard of care in multiple indications with mechanisms and targeted disease states for which our team has significant relevant experience.

We are committed to utilizing our valuable human and financial capital efficiently to achieve our mission of identifying, acquiring, and accelerating the development and commercialization of transformative medicines in areas of significant unmet patient need.

License and Collaboration Agreements

License and Collaboration Agreement with Affibody

On August 9, 2021, we entered into a license agreement with Affibody AB (Affibody) (the Affibody Agreement), under which Affibody granted us exclusive, sublicensable licenses to develop, commercialize and manufacture products containing izokibep for all human therapeutic uses on a worldwide basis, subject to a pre-existing agreement with Inmagene Biopharmaceuticals (Inmagene) with respect to certain Asian countries as described below (the Inmagene Agreement).

A global joint steering committee (GJSC) oversees the global development of izokibep. The GJSC is composed of designees from Affibody, Inmagene and us. We chair the GJSC and retain final decision-making authority for izokibep global development. In exercising this decision-making authority, we are obligated to use commercially reasonable efforts (i) to develop products containing izokibep worldwide, excluding in the Inmagene Development Territory as defined below, (ii) for the conduct and finalization of certain ongoing clinical trials, and (iii) to commercialize products containing izokibep for all human therapeutic uses worldwide, except in the Inmagene Commercialization Territory as defined below, after obtaining the applicable marketing authorization. We are responsible for manufacturing both the clinical and commercial supply of licensed product globally.

Affibody also granted us a non-exclusive license with respect to certain platform intellectual property owned or controlled by Affibody. Under the Affibody Agreement, we granted an exclusive, sublicensable license to Affibody under certain of our know-how, patents and trademarks to develop and commercialize products containing izokibep for all human therapeutic uses in the Inmagene Development Territory and Inmagene Commercialization Territory (collectively, the Inmagene Territory), respectively. We also granted Affibody a non-exclusive, sublicensable license under certain know-how and patents to commercialize such products for all human therapeutic uses in the Affibody Co-Commercialization Territory (as defined below). To the extent any rights under the Inmagene Agreement terminate with respect to the Inmagene Development Territory or Inmagene Commercialization Territory, Affibody has also granted us an option to acquire such rights as well as a right of first refusal with respect to any transaction with a third party to acquire such rights. Under the Affibody Agreement, Affibody has also retained the option to co-promote izokibep in Denmark, Finland, Iceland, Norway, and Sweden (the Affibody Co-Commercialization Territory). Affibody is obligated to notify us of its decision whether to co-promote izokibep in the Affibody Co-Commercialization Territory within three months following the dosing of 15% of participants in the first pivotal trial for izokibep, and we also grant Affibody a right of first negotiation to expand the Affibody Co-Commercialization Territory to include all countries of the European Union and the United Kingdom.

As consideration for the Affibody Agreement (EU), we have paid Affibody an aggregate upfront fee of $25 million. In addition, we are required to pay an aggregate of up to $280 million, $30 million of which would be due prior to the first approval in the United States, upon the achievement of various development, regulatory and commercialization milestones with respect to the licensed products. We are also obligated to pay high single-digit to low-teen royalties to Affibody on net sales of licensed products in the territory where we have commercialization rights, subject to reduction in certain circumstances. Royalties will be payable on a licensed product-by-licensed product and country-by-country basis for a period commencing upon the first commercial sale of the licensed product worldwide, except in the Inmagene Commercialization Territory, and continuing until the later of (a) the expiration of all valid patent claims or regulatory exclusivity covering the licensed product in that country and (b) ten (10) years after such first commercial sale.

In the event the FDA grants us or our affiliates or sublicensees a priority review voucher for a licensed product, we will pay Affibody either: (a) if we sell or transfer such priority review voucher to a third-party, approximately one third of the proceeds we receive from the sale, net of taxes, or (b) if we use the priority review voucher for an indication or product outside the scope of the Affibody Agreement, approximately one third of the fair market value of the priority review voucher as determined in accordance with the Affibody Agreement.

Unless earlier terminated, the Affibody Agreement will continue on a licensed product-by-licensed product basis and country-by-country basis until there are no more royalty payments owed to Affibody on any licensed product thereunder. Either party may terminate the Affibody Agreement upon an uncured material breach by, or upon the bankruptcy, reorganization, liquidation or receivership proceedings of, the other party. In addition, each party may terminate the agreement upon 30 days' written notice in the event that certain clinical events create a serious and material risk of compromising patient safety. Either party may also terminate the agreement if the other party or any of its affiliates institutes a patent challenge against certain background patent rights for licensed products. The Affibody Agreement may also be terminated by us for convenience (i) upon 90 days' prior written notice to Affibody if the termination is before the first commercial sale of a licensed product, or (ii) upon 180 days' prior written notice if the termination is after the first commercial sale of a licensed product.

Under the Inmagene Agreement and subject to the terms of the Affibody Agreement, Affibody granted Inmagene (i) commercialization rights in Mainland China, Hong Kong, Macau, Taiwan and South Korea (the Inmagene Commercialization Territory) and (ii) development rights in Mainland China, Hong Kong, Macau, Taiwan, South Korea, and certain other Asia-Pacific countries (the Inmagene Development Territory). As described above, the global development plan is governed by the GJSC.

License and Commercialization Agreement with Pierre Fabre

Upon the closing of the merger with ValenzaBio, we became successors to ValenzaBio's rights under the March 25, 2021 license and commercialization agreement between ValenzaBio and Pierre Fabre Medicament SAS (Pierre Fabre), as amended (the Pierre Fabre Agreement). Under the Pierre Fabre Agreement, Pierre Fabre granted to ValenzaBio certain exclusive worldwide (subject to a reversion option, as described below), sublicensable rights and licenses to certain patents, know-how and other intellectual property to develop, manufacture, use and commercialize a specific naked anti-IGF-1R monoclonal antibody, which we refer to as lonigutamab, for non-oncology therapeutic indications. Our license from Pierre Fabre extends to any product containing lonigutamab (excluding any fragments or derivatives) as its sole active ingredient (each, a PF Licensed Product). The Pierre Fabre Agreement prohibits us from using the licensed intellectual property in any antibody drug conjugate (ADC), multi-specific antibodies or any other derivatives of lonigutamab. Under the Pierre Fabre Agreement, we are required to obtain certain rights under intellectual property owned by Lonza Sales AG (Lonza) in order to exploit the PF Licensed Product, and we have been granted a non-exclusive sublicense to such rights necessary to initiate the development activities under the Pierre Fabre Agreement.

In the event we decide to sublicense the rights to develop or commercialize a PF Licensed Product in any territory outside of the United States and Canada (collectively, the Option Territory), Pierre Fabre retains the right of first negotiation to acquire such development and commercialization rights in one or more countries in the Option Territory.

Within six months after the joint steering committee (JSC) validates that pre-defined clinical trial criteria for the first proof of concept clinical trial for a PF Licensed Product has been achieved:

- Pierre Fabre has the option (the Option) to reclaim all exclusive rights to develop, commercialize and exploit the PF Licensed Product in the Option Territory and to obtain an exclusive sublicensable license in the Option Territory for any improvements and trademarks to such PF Licensed Product, and to exploit such PF Licensed Product for non-oncology therapeutic indications, subject to certain payment obligations of Pierre Fabre to us. If Pierre Fabre exercises the Option for a PF Licensed Product in the Option Territory, and intends to sublicense such rights, then we will have the right of first negotiation to acquire such development and commercialization rights in the Option Territory;
- Pierre Fabre has the right to require us to buy out its right to the Option for a one-time payment of $31 million (the Option Buy Out Payment); or
- We have the right to choose to buy out Pierre Fabre's Option by making the Option Buy Out Payment to Pierre Fabre within 30 days from Pierre Fabre's notice of exercise of the Option.

If Pierre Fabre does not exercise the Option within the option period or if we buy out Pierre Fabre's right to the Option, the Option will expire or terminate, respectively. We are solely responsible for the development, regulatory approvals and commercialization of each PF Licensed Product except to the extent that Pierre Fabre reclaims rights to a PF Licensed Product in the Option Territory as described above. Prior to the exercise of the Option, ACELYRIN has the right to cast the deciding vote at the JSC subject to certain limitations. After exercise of the option, ACELYRIN has final decision making authority with respect to global development subject to certain limitations and except that Pierre Fabre has final decision making authority with respect to regulatory activities and commercialization in the Option Territories provided these decisions comply with the agreed development principles and these decisions are not likely to have a material adverse impact on commercialization of the PF Licensed Product in the United States.

We are obligated to use commercially reasonable efforts to (i) develop the PF Licensed Product for non-oncology therapeutic indications in the licensed territory, (ii) achieve certain development milestones, (iii) complete a successful subcutaneous feasibility study and to file an Investigational New Drug Application (IND) within certain timelines, (iv) submit a complete set of data and documents with respect to the proof of concept clinical study for JSC review and (v) commercialize PF Licensed Product for non-oncology therapeutic indications in the licensed territory, with certain exclusions.

In connection with the original Pierre Fabre Agreement, ValenzaBio made an aggregate license payment of $7.5 million to Pierre Fabre, and issued Pierre Fabre 1,053,319 shares of ValenzaBio's Series A Preferred Stock. As consideration for the amendment to the original Pierre Fabre Agreement, we paid Pierre Fabre an aggregate license payment of $10 million. Furthermore, in connection with the closing of the merger with ValenzaBio, Pierre Fabre's Series A Preferred Stock in ValenzaBio was converted into 1,667,326 shares of our Class A Common Stock. In addition, as successors to the Pierre Fabre Agreement, we are required to pay an aggregate of up to $99.5 million upon the achievement of various development and regulatory milestones, approximately $40 million of which would be due prior to the first approval in the United States. We are also obligated to pay up to an aggregate of $390 million upon the achievement of certain commercial milestones. We must also pay tiered royalties in the high single-digit to low-teen percentages to Pierre Fabre on worldwide net sales in a given calendar year, subject to certain reductions. Royalties will be payable for each PF Licensed Product in a given country during a period commencing upon the first commercial sale of such PF Licensed Product in such country and continuing until the latest of (a) 10 years after such first commercial sale, (b) expiration of last-to-expire valid claim in a licensed patent in such country and (c) expiration of regulatory exclusivity for such PF Licensed Product in such country. In the event we enter into a sublicense with a third party, we must also share with Pierre Fabre a percentage of any revenues from option fees, upfront payments, license maintenance fees, milestone payments or the like generated from the sublicense. Such percentage may be between the high single-digits to the low thirties based on which stage of development of a PF Licensed Product the sublicense is entered into.

Unless earlier terminated, the Pierre Fabre Agreement will continue on a PF Licensed Product-by-PF Licensed Product and country-by-country basis until there are no more royalty payments owed to Pierre Fabre on any PF Licensed Product thereunder. Either party may terminate the Pierre Fabre Agreement upon an uncured material breach, or upon the bankruptcy or insolvency of the other party. Pierre Fabre may also terminate the agreement if we or any of our affiliates institutes a patent challenge against the licensed patents from Pierre Fabre. We may also terminate the Pierre Fabre Agreement with or without cause upon nine months' prior written notice, so long as there is no ongoing clinical trial for any PF Licensed Product.

Intellectual Property

We strive to protect and enhance the proprietary technology, inventions and improvements that are commercially important to our business, including seeking, maintaining, enforcing and defending patent rights, whether developed internally or licensed from our collaborators or other third parties. Our policy is to seek to protect our proprietary position by, among other methods, filing patent applications in the United States and in jurisdictions outside of the United States related 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, continuing innovation, and in-licensing opportunities to develop, strengthen and maintain our proprietary position in the field of immunology; however, trade secrets are difficult to protect and provide us with only limited protection. Our commercial success may 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 maintain our licenses to use intellectual property owned by third parties; and to defend and enforce our proprietary rights, including our patents.

We have in-licensed and procured patents and patent applications, which include claims directed to compositions covering our product candidates and methods of manufacturing such compositions. As of January 6, 2023, our owned and exclusively licensed patent portfolio included eight issued U.S. patents, 140 issued foreign patents, three pending provisional U.S. patent applications, four pending non-provisional U.S. patent applications and 44 pending foreign patent applications.

Our patent portfolio in general includes patents and patent applications directed to our lead product candidate, izokibep, as well as to our other product candidates, lonigutamab and XLRN-517.

Izokibep

With respect to izokibep, as of January 6, 2023, we exclusively in-licensed six issued U.S. patents, three pending U.S. non-provisional applications, at least 98 corresponding foreign patents and at least 25 foreign patent applications directed to composition of matter and processes of preparation of proteins from Affibody under the Affibody Agreement. The six issued patents are expected to expire between 2028 and 2036 and any patents that issue from such patent applications are expected to expire between 2034 and 2040, without taking into account any possible patent term adjustment or extensions and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees. In addition, as of January 6, 2023, we owned two pending U.S. provisional patent applications directed to methods of treatment of ailments by administration of izokibep. Patents, if issued from such provisional applications (assuming conversion of the provisional application to a non-provisional U.S. application and/or Patent Cooperation Treaty (PCT) filing with a subsequent U.S. National Phase application), are expected to expire in 2043, without giving effect to any potential patent term extensions and patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

Lonigutamab

With respect to lonigutamab, as of January 6, 2023, we exclusively in-licensed through ValenzaBio from Pierre Fabre under the Pierre Fabre Agreement two issued U.S. patents, one pending U.S. provisional application, at least 42 corresponding foreign patents and at least 19 foreign patent applications in Europe, Australia, Canada, China, India, Japan, South Africa, Brazil, Republic of Korea, Egypt, United Arab Emirates, Israel, New Zealand, Malaysia, Russia, Thailand, Austria, Belgium, Croatia, Denmark, France, Germany, Greece, United Kingdom, Italy, Ireland, Spain, Norway, Netherlands, Poland, Portugal, Serbia, Switzerland, Hong Kong, and Sweden directed to composition of matter. Such issued patents are expected to expire in 2035 and any patents, if issued from such provisional application (assuming conversion of the provisional application to a non-provisional U.S. application and/or PCT filing with a subsequent U.S. National Phase application), are expected to expire in 2043, without giving effect to any potential patent term extensions and patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

XLRN-517

With respect to XLRN-517, as of January 6, 2023, we exclusively in-licensed one pending non-provisional U.S. patent application directed to composition of matter through ValenzaBio from Novelty Nobility, Inc. This patent application, should it issue as a U.S. patent, is expected to expire in 2039, without taking into account any possible patent term adjustment or extensions and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees. Corresponding patent applications are also being pursued in Australia, Canada, China, Europe, and Republic of Korea, and are licensed through ValenzaBio from Novelty Nobility, Inc. We do not currently own or license any issued patents with claims directed to XLRN-517 and there can be no assurance that we will obtain any issued patents directed to XLRN-517.

We continue to assess the extent to which we may seek additional patent protection for aspects of our product engine. The term of individual patents depends upon the date of filing of the patent application, date of patent issuance and the legal term of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the earliest date of filing of the first non-provisional application to which priority is claimed. Outside of the United States, the duration of patents varies in accordance with applicable local law, but typically is also 20 years from the earliest non-provisional filing date. In the United States, patent term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the United States Patent and Trademark Office (USPTO) in examining and granting a patent, or may be shortened if a patent is terminally disclaimed over an earlier-filed patent. Moreover, in context of approved products, there may be other additional exclusivity for the patents covering such approved product. In the United States, the term of a patent that covers an FDA-approved drug may also be eligible for a patent

term extension of up to five years under the Hatch-Waxman Act, which is designed to compensate for the patent term lost during the FDA regulatory review process. The length of the patent term extension is calculated based on the length of time it takes for regulatory review. A patent term extension under the Hatch-Waxman Act cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent applicable to an approved drug may be restored and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. Moreover, a patent can only be restored once, and thus, if a single patent is applicable to multiple products, it can only be extended based on one product. Similar provisions are available in Europe and certain other foreign jurisdictions to extend the term of a patent that covers an approved drug.

We intend to pursue, in the normal course of business and when possible, composition, method of use, process, dosing and formulation patent protection for the product candidates we develop and commercialize. We may also pursue patent protection with respect to manufacturing and immunotherapy development processes and technology. When available to expand market exclusivity, we intend to strategically obtain or license additional intellectual property related to current or contemplated product candidates.

In some instances, we submit patent applications directly to the USPTO as provisional patent applications. Corresponding non-provisional patent applications must be filed within 12 months after the provisional application filing date. The corresponding non-provisional application may be entitled to the benefit of the earlier provisional application filing date(s), and the patent term of the finally issued patent is calculated from the later non-provisional application filing date. Provisional applications for patents were designed to provide a lower-cost first patent filing in the United States. This system allows us to obtain an early priority date, add material to the patent application(s) during the priority period, obtain a later start to the patent term and to delay prosecution costs.

The PCT system allows a single application to be filed within 12 months of the original priority date of the patent application, and to designate all of the PCT member states in which national or regional patent applications can later be pursued based on the international patent application filed under the PCT. The PCT searching authority performs a patentability search and issues a non-binding patentability opinion which can be used to evaluate the chances of success for the national or regional applications prior to having to incur the filing fees and prosecution costs. Although a PCT application does not issue as a patent, it allows the applicant to seek protection in any of the member states through national/regional-phase applications. At the end of the period of two and a half years from the first priority date of the patent application, separate patent applications can be pursued in any of the PCT member states either by direct national filing or, in some cases by filing through a regional patent organization, such as the European Patent Organisation. The PCT system delays expenses, allows a limited evaluation of the chances of success for national/regional patent applications and enables substantial savings where applications are abandoned within the first two and a half years of filing. We intend to file U.S. nonprovisional applications and PCT applications that claim the benefit of the priority date of earlier filed provisional applications, when applicable.

For all patent applications, we determine claiming strategy on a case-by-case basis. Advice of counsel, country-specific patent laws and our business model and needs are always considered. We may file patents containing claims for protection of all useful applications of our proprietary product candidates, as well as all new applications and/or uses we discover for existing product candidates, assuming these are strategically valuable. We continuously reassess the number and type of patent applications in our portfolio, as well as the pending and issued patent claims, to help ensure that maximum coverage and value are obtained for our processes, and compositions, given existing patent office rules and regulations. Further, claims may be modified during patent prosecution, to the extent allowed, to meet our intellectual property and business needs.

There can be no assurance that we will be able to obtain, maintain, enforce and defend all patents and other intellectual property rights necessary to conduct our business. The patents we in-license, or patents that issue from our owned patent applications, if any, may be challenged by third parties, may not effectively prevent third parties from commercializing competitive technologies or may not otherwise provide us with a competitive advantage. For more information regarding the risks related to our intellectual property, see section titled "Risk Factors—Risks Related to Intellectual Property."

Sales, Marketing and Commercialization

We hold global development and commercialization rights to izokibep (excluding certain Asian countries including mainland China, Hong Kong, South Korea and Taiwan) and we hold global development and commercialization rights to lonigutamab outside of oncology. None of our product candidates have been approved for sale. If our product candidates receive marketing approval, we intend to commercialize them on our own, or jointly with a partner, in the United States and potentially in other geographies. We will continually evaluate the economics of commercializing our product candidates versus other strategic commercialization arrangements.

We currently have no sales, marketing or commercialization capabilities and have no experience as a company performing such activities. However, we intend to build the necessary capabilities and infrastructure over time as our product candidates continue to advance through clinical development. Clinical data, the size of the opportunity and the size of the commercial infrastructure required will influence our commercialization plans and decision making.

Manufacturing

We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We have engaged, and expect to continue to rely on, well-established third-party contract manufacturing organizations (CMOs), to supply our product candidates for use in our preclinical studies and clinical trials. Should any of these CMOs become unavailable to us for any reason, we believe that there are a number of potential replacements, although we may incur some delay in identifying and qualifying such replacements.

Additionally, we intend to rely on third-party CMOs for commercial manufacturing, if our product candidates receive marketing approval. As our lead product candidates izokibep and lonigutamab advance through development, we expect to enter into longer-term commercial supply agreements to fulfill and secure our production needs. As we advance our product candidates through development, we will consider our lack of redundant supply for the drug substance and drug product for each of our product candidates to mitigate the risk of supply disruptions. While the drug substances used in our product candidates are manufactured by more than one supplier, the number of manufacturers is limited. In the event it is necessary or advisable to acquire supplies from an alternative supplier, we might not be able to obtain them on commercially reasonable terms, if at all. It could also require significant time and expense to redesign our manufacturing processes to work with another company. If we need to change manufacturers during the clinical or development stage for product candidates or after commercialization for our product candidates, if approved, the FDA and corresponding foreign regulatory agencies must approve these new manufacturers in advance, which will involve testing and additional inspections to ensure compliance with FDA regulations and standards and may require significant lead times and delay.

Additionally, to adequately meet our projected commercial manufacturing needs, for izokibep, our CMOs will need to scale-up production, or we will need to secure additional suppliers and we anticipate the same may be required for lonigutamab as that product candidate progresses through develop. Processes for producing drug substances and drug product for commercial supply are currently being developed, with the goal of achieving reliable, reproducible, and cost-effective production. We believe the drug substance and drug product processes for izokibep and lonigutamab are amenable to scale-up.

Government Regulation

Government authorities in the United States at the federal, state and local level and in other countries regulate, among other things, the research, development, manufacturing, testing, quality control, approval, labeling and packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing, and export and import of biological products. Generally, before a new biologic can be marketed, data demonstrating its quality, safety and efficacy must be obtained, organized into a format specific for each regulatory authority, submitted for review and approved by the applicable regulatory authority.

Government Regulation of Biological Products

In the United States, the FDA regulates biologics under the Federal Food, Drug, and Cosmetic Act (FDCA), the Public Health Service Act (PHSA), and their implementing regulations. Biologics also are subject to other federal, state and local statutes and regulations, such as those related to competition. The process of obtaining regulatory approvals and the subsequent compliance with appropriate statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the development process, approval process or following any potential approval, may subject an applicant to administrative actions or judicial sanctions. These actions and sanctions could include, among other actions, the FDA's refusal to approve pending applications, license revocation, a clinical hold, untitled or warning letters, voluntary or mandatory product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement and civil or criminal fines or penalties.

Our product candidates must be approved by the FDA through a Biologics License Application (BLA) process before they may be legally marketed in the United States. The process generally involves the following:

- completion of extensive preclinical studies in accordance with applicable regulations, including studies conducted in accordance with Good Laboratory Practices (GLP) requirements;
- submission to the FDA of an Investigational New Drug application (IND), which must become effective before human clinical trials may begin;
- approval by an Institutional Review Boards (IRBs) at each clinical trial site before each human trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with applicable IND regulations, Good Clinical Practices (GCP) requirements and other clinical trial-related regulations to establish the safety and efficacy of the product candidate for each proposed indication;
- submission to the FDA of a BLA, and payment of the applicable user fee for FDA review of such BLA;
- a determination by the FDA within 60 days of its receipt of the BLA to accept the filing for review;
- satisfactory completion of one or more FDA pre-approval inspections of the manufacturing facility or facilities where the product candidate will be produced to assess compliance with Current Good Manufacturing Practices (cGMP), requirements to assure that the facilities, methods and controls are adequate to preserve the product candidate's identity, strength, quality and purity;
- potential FDA audit of the clinical trial sites that generated the data in support of the BLA; and
- FDA review and approval of the BLA, including consideration of the views of any FDA advisory committee, prior to any commercial marketing or sale of the product in the United States.

The preclinical and clinical testing and approval process requires substantial time, effort and financial resources. The regulatory scheme for biologics is evolving and subject to change at any time, and can be affected by changes in medical treatment standards of care.

Preclinical Studies

Before testing any product candidate in humans, it must undergo rigorous preclinical testing. Preclinical studies include laboratory evaluation of its chemistry and formulation, as well as *in vitro* and animal studies to assess safety and in some cases to establish a rationale for therapeutic use. The conduct of preclinical studies is subject to federal and state regulations and requirements, including GLP regulations for safety/toxicology studies.

An IND sponsor must submit the results of the preclinical studies, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical trials, among other things, to the FDA as part of an IND. An IND is an application to the FDA, seeking authorization to administer an investigational product to humans, and it must become effective before human clinical trials may begin. Some long-term preclinical testing, such as animal tests of reproductive adverse events and carcinogenicity, may continue after the IND is submitted. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time, the FDA raises concerns or questions related to one or more proposed clinical trials and places the trial on clinical hold. In such a situation, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence, or may require a substantial amount of time to resolve FDA concerns.

Clinical Trials

The clinical stage of development involves the administration of the investigational product to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control, in accordance with GCP requirements, which include the requirement that all trial subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria and the methods to be used to monitor subject safety and assess efficacy. Each protocol, and any subsequent amendments to the protocol, must be submitted to the FDA as part of the IND. Furthermore, each clinical trial must be reviewed and approved by an IRB for each institution at which the clinical trial will be conducted to ensure that the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative, and must monitor the clinical trial until completed. There also are requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries. Information about certain clinical trials, including clinical trial results, must be submitted within specific timeframes for publication on the www.clinicaltrials.gov website.

A sponsor who wishes to conduct a clinical trial outside of the United States may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. If a foreign clinical trial is not conducted under an IND, the sponsor may still submit data from the clinical trial to the FDA in support of a BLA. The FDA will accept a well-designed and well-conducted foreign clinical trial not conducted under an IND if the study was conducted in accordance with GCP requirements, and the FDA is able to validate the data through an onsite inspection if deemed necessary. For a marketing application based solely on foreign clinical data, the FDA considers whether the study data are applicable to the United States given possible differences in medical practice and patient populations.

Clinical trials generally are conducted in three sequential phases, known as Phase 1, Phase 2 and Phase 3, and may overlap.

- Phase 1 clinical trials generally involve a small number of healthy volunteers or disease-affected patients who are initially exposed to a single dose and then multiple doses of the product candidate. The primary purpose of these clinical trials is to assess the metabolism, pharmacologic action, side effect tolerability and safety of the product candidate.

- Phase 2 clinical trials involve studies in disease-affected patients to evaluate proof of concept and determine the dose required to produce the desired benefits. At the same time, safety and further PK and PD information is collected, possible adverse effects and safety risks are identified, and a preliminary evaluation of efficacy is conducted.
- Phase 3 clinical trials generally involve a large number of patients at multiple sites and are designed to provide the data necessary to demonstrate the effectiveness of the product candidate for its intended use, its safety in use and to establish the overall benefit/risk relationship of the product candidate and provide an adequate basis for product labeling.

Post-approval trials, sometimes referred to as Phase 4 clinical trials, 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 and are commonly intended to generate additional safety data regarding use of the product in a clinical setting. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of BLA approval.

Progress reports detailing the results of the clinical trials, among other information, must be submitted at least annually to the FDA and written IND safety reports must be submitted to the FDA and the investigators 15 days after the trial sponsor determines the information qualifies for reporting for suspected and unexpected serious adverse reactions, findings from other studies or animal or in vitro testing that suggest a significant risk for human participants and any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must also notify the FDA of any unexpected fatal or life- threatening suspected adverse reaction as soon as possible but in no case later than seven calendar days after the sponsor's initial receipt of the information.

Phase 1, Phase 2, Phase 3 and other types of clinical trials may not be completed successfully within any specified period, if at all. The FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the trial participants 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 product candidate has been associated with unexpected serious harm to patients. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether a trial may move forward at designated check points based on access to certain data from the trial. Concurrent with clinical trials, companies usually complete additional animal studies and also must develop additional information about the chemistry and physical characteristics of the product candidate as well as 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 and, among other things, companies must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidates do not undergo unacceptable deterioration over their shelf life.

FDA Review Process

Following completion of the clinical trials, data are analyzed to assess whether the investigational product is safe and effective for the proposed indicated use or uses. The results of preclinical studies and clinical trials are then submitted to the FDA as part of a BLA, along with proposed labeling, chemistry and manufacturing information to ensure product quality and other relevant data. The BLA is a request for approval to market the biologic for one or more specified indications and must contain proof of safety, purity and potency. The application may include both negative and ambiguous results of preclinical studies and clinical trials, as well as positive findings. Data may come from company-sponsored clinical trials intended to test the safety and efficacy of a product's use or from a number of alternative sources, including studies initiated by investigators. To

support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of the investigational product to the satisfaction of the FDA. FDA approval of a BLA must be obtained before a biologic may be marketed in the United States.

Under the Prescription Drug User Fee Act, as amended (PDUFA), a BLA must be accompanied by a user fee. The FDA adjusts the PDUFA user fees on an annual basis. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on BLAs for products designated as orphan drugs, unless the BLA also includes a non-orphan indication.

The FDA reviews all submitted BLAs before it accepts them for filing, and may request additional information rather than accepting the BLA for filing. The FDA must make a decision on accepting a BLA for filing within 60 days of receipt, and such decision could include a refusal to file by the FDA. Once and if the submission is accepted for filing, the FDA begins an in-depth review of the BLA. Under the goals and policies agreed to by the FDA under PDUFA, the FDA targets ten months, from the filing date, in which to complete its initial review of an original BLA and respond to the applicant, and six months from the filing date of an original BLA designated for priority review. The FDA does not always meet its PDUFA goal dates for standard and priority BLAs, and the review process is often extended by FDA requests for additional information or clarification.

Before approving a BLA, the FDA will conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether they comply with cGMP requirements. The FDA will not approve the product 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. The FDA also may audit data from clinical trials to ensure compliance with GCP requirements and confirm such data are intended to evaluate the integrity of clinical data. Additionally, the FDA may refer applications for novel products or products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions, if any. The FDA is not bound by recommendations of an advisory committee, but it considers such recommendations when making decisions on approval. The FDA likely will reanalyze the clinical trial data, which could result in extensive discussions between the FDA and the applicant during the review process. After the FDA evaluates a BLA, it will issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the product with specific 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 all of the specific deficiencies in the BLA identified by the FDA. The Complete Response Letter may require the applicant to obtain additional clinical data, including the potential requirement to conduct additional pivotal Phase 3 clinical trial(s) and to complete other significant and time-consuming requirements related to clinical trials, or to conduct additional preclinical studies or manufacturing activities. If a Complete Response Letter is issued, the applicant may either resubmit the BLA, addressing all of the deficiencies identified in the letter, or withdraw the application or request an opportunity for a hearing. Even if such requested data and information are submitted, the FDA may decide that the BLA does not satisfy the criteria for approval.

Orphan Drug Designation and Exclusivity

Under the Orphan Drug Act, the FDA may grant orphan designation to a biological product intended to treat a rare disease or condition, which is a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making the product available in the United States for this type of disease or condition will be recovered from sales of the product.

Orphan drug designation must be requested before submitting a BLA. After the FDA grants orphan drug designation, the identity of the product candidate and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product candidate that has orphan drug designation subsequently receives the first FDA approval for the disease or condition 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 to market the same product for the same indication for seven years from the date of such approval, except in limited circumstances, such as a showing of clinical superiority to such product by means of greater effectiveness, greater safety or providing a major contribution to patient care or in instances of supply issues. Competitors, however, may receive approval of either a different product for the same indication or the same product for a different indication but that could be used off-label in the orphan indication. Orphan drug exclusivity also could block the approval of one of our product candidates for seven years if a competitor obtains approval before we do for the same product, as defined by the FDA, for the same indication we are seeking approval, or if our such product candidate is determined to be contained within the scope of the competitor's product for the same indication or disease. If we pursue marketing approval for an indication broader than the orphan drug designation we have received, we may not be entitled to orphan drug exclusivity. Orphan drug status in the EU has similar, but not identical, requirements and benefits.

Other Expedited Development and Review Programs

A sponsor may seek to develop and obtain approval of its product candidates under programs designed to accelerate the development, FDA review and approval of product candidates that meet certain criteria. For example, the FDA has a Fast Track program that is intended to expedite or facilitate the process for reviewing new drugs and biologics that are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the condition. Fast Track designation applies to both the product and the specific indication for which it is being studied. For a Fast Track-designated biological product, the FDA may consider sections of the BLA for review on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the application, the FDA agrees to accept sections of the application and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the application. The sponsor can request the FDA to designate the product for Fast Track status any time before receiving BLA approval, but ideally no later than the pre-BLA meeting.

A product submitted to the FDA for marketing authorization, including under a Fast Track program, may be eligible for other types of FDA programs intended to expedite development or review, such as priority review. Priority review means that, for an original BLA, the FDA sets a target date for FDA action on the marketing application at six months after accepting the application for filing as opposed to ten months. A product is eligible for priority review if it is designed to treat a serious or life-threatening disease condition and, if approved, would provide a significant improvement in safety and effectiveness compared to available therapies. If criteria are not met for priority review, the application for an original BLA is subject to the standard FDA review period of ten months after FDA accepts the application for filing. Priority review designation does not change the scientific/medical standard for approval or the quality of evidence necessary to support approval.

Additionally, a biologic may be eligible for designation as a breakthrough therapy if the product candidate is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening condition and preliminary clinical evidence indicates that the product candidate may demonstrate substantial improvement over currently approved 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

product candidate to ensure that the development program to gather the preclinical and clinical data necessary for approval is as efficient as practicable; 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. Breakthrough therapy designation comes with the benefits of Fast Track designation, which means that the sponsor may file sections of the BLA for review on a rolling basis if certain conditions described above are satisfied.

Even if a product candidate qualifies for one or more of these programs, the FDA may later decide that the product candidate no longer meets the conditions for qualification or the time period for FDA review or approval may not be shortened. Furthermore, Fast Track designation, priority review, and breakthrough therapy designation do not change the standards for approval.

Pediatric Information and Pediatric Exclusivity

Under the Pediatric Research Equity Act (PREA), certain BLAs and certain supplements to a BLA must contain data to assess the safety and efficacy of the product candidate for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product candidate is safe and effective. The FDA may grant deferrals for submission of pediatric data or full or partial waivers. A sponsor who is planning to submit a marketing application for a biologic that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration must submit an initial Pediatric Study Plan (PSP), within 60 days of an end-of-Phase 2 meeting or, if there is no such meeting, as early as practicable before the initiation of the Phase 3 or Phase 2/3 study. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. The FDA and the sponsor must reach an agreement on the PSP. A sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from preclinical studies, early phase clinical trials and other clinical development programs.

A biologic product can also obtain pediatric market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study.

Post-Marketing Requirements

Following approval of a new product, the manufacturer and the approved product are subject to continuing regulation by the FDA, including, among other things, monitoring and record-keeping activities, reporting of adverse experiences, complying with promotion and advertising requirements, which include restrictions on promoting products for unapproved uses or patient populations (known as "off-label use") and limitations on industry-sponsored scientific and educational activities. Although physicians may prescribe legally available products for off-label uses, manufacturers may not market or promote such uses. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability, including investigation by federal and state authorities. Prescription drug promotional materials must be submitted to the FDA in conjunction with their first use or first publication. Further, if there are any modifications to the product, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new BLA or BLA supplement, which may require the development of additional data or preclinical studies and clinical trials.

The FDA may also place other conditions on approvals including the requirement for a Risk Evaluation and Mitigation Strategy (REMS), to assure the safe use of the product. If the FDA concludes a REMS is needed, the FDA will not approve the BLA without the sponsor's submission of a proposed REMS, and FDA approval thereof. 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. Product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following initial marketing.

FDA regulations require that products be manufactured in specific approved facilities and in accordance with cGMP regulations. We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our products in accordance with cGMP regulations. These manufacturers must comply with cGMP regulations that require, among other things, quality control and quality assurance, the maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Manufacturers and other entities involved in the manufacture and distribution of approved biologics 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 requirements and other laws. Manufacturers and other parties involved in the drug supply chain for prescription drug products must also comply with product tracking and tracing requirements and for notifying the FDA of counterfeit, diverted, stolen and intentionally adulterated products or products that are otherwise unfit for distribution in the United States. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance. The discovery of violative conditions, including failure to conform to cGMP regulations, could result in enforcement actions, and the discovery of problems with a product after approval may result in restrictions on a product, manufacturer or holder of an approved BLA, including recall.

Once an approval is granted, the FDA may issue enforcement letters or revoke the approval of the product if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Corrective action could delay product distribution and require significant time and financial expenditures. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among others:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve applications or supplements to approved applications, or suspension or revocation of product approvals; product seizure or detention, or refusal to permit the import or export of product; or
- injunctions or the imposition of civil or criminal penalties.

Biosimilars and Exclusivity

Our product candidates, including izokibep and lonigutamab, are regulated as biologics. An abbreviated approval pathway for biological products shown to be similar to, or interchangeable with, an FDA-licensed reference biological product was created by the Biologics Price Competition and Innovation Act of 2009, as part of the Affordable Care Act. This amendment to the PHSA, in part, attempts to minimize duplicative testing. Biosimilarity, which requires that the biological product be highly similar to the reference product notwithstanding minor differences in clinically inactive components and that there be no clinically meaningful differences between the product and the reference product in terms of safety, purity and potency, can be shown

through analytical studies, animal studies and a clinical trial or trials. Interchangeability requires that a biological product be biosimilar to the reference product and that the product can be expected to produce the same clinical results as the reference product in any given patient and, for products administered multiple times to an individual, that the product and the reference product may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biological product without such alternation or switch.

The FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product, and the FDA will not approve an application for a biosimilar or interchangeable product based on the reference biological product until twelve years after the date of first licensure of the reference product. "First licensure" typically means the initial date the particular product at issue was licensed in the United States. Date of first licensure does not include the date of licensure of (and a new period of exclusivity is not available for) a biological product if the licensure is for a supplement for the biological product or for a subsequent application by the same sponsor or manufacturer of the biological product (or licensor, predecessor in interest, or other related entity) for a change (not including a modification to the structure of the biological product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device or strength, or for a modification to the structure of the biological product that does not result in a change in safety, purity, or potency. Therefore, one must determine whether a new product includes a modification to the structure of a previously licensed product that results in a change in safety, purity, or potency to assess whether the licensure of the new product is a first licensure that triggers its own period of exclusivity. Whether a subsequent application, if approved, warrants exclusivity as the "first licensure" of a biological product is determined on a case-by-case basis with data submitted by the sponsor.

Other United States Healthcare Laws

Healthcare providers and third-party payors in the United States and elsewhere play a primary role in the recommendation and prescription of pharmaceutical products. Arrangements with third-party payors and customers can expose pharmaceutical supply to broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation:

- The federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under the Medicare and Medicaid programs, or other federal healthcare programs. A person or entity can be found guilty of violating the statute without actual knowledge of the statute or specific intent to violate it. 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 False Claims Act (FCA). The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, but such exceptions and safe harbors are drawn narrowly and require strict compliance in order to offer protection;
- The federal civil and criminal false claims laws, including the FCA, and civil monetary penalty laws, which prohibit any person or entity from, among other things, knowingly presenting, or causing to be presented, a false, fictitious or fraudulent claim for payment to, or approval by, the federal government or knowingly making, using or causing to be made or used a false record or statement, including providing inaccurate billing or coding information to customers or promoting a product off-label, material to a false or fraudulent claim to the federal government. A claim includes "any request or demand" for money or property presented to the federal government. In addition, manufacturers can be

held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. The FCA also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery;

- The federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), which created federal criminal statutes that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity can be found guilty of violating HIPAA without actual knowledge of the statute or specific intent to violate it;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH), and their respective implementing regulations, which impose, among other things, specified requirements relating to the privacy, security and transmission of individually identifiable health information held by covered entities and their business associates as well as their covered subcontractors. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;
- The federal legislation commonly referred to as the Physician Payments Sunshine Act, created under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the ACA), and its implementing regulations, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the Centers for Medicare & Medicaid Services, (CMS), information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors) and certain other practitioners, including physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse midwives, and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members.
- Federal government price reporting laws, which require us to calculate and report complex pricing metrics in an accurate and timely manner to government programs;
- Analogous state laws and regulations, including: state anti-kickback and false claims laws, which may apply to our business practices, including, but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state and local laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; state laws that require the reporting of information related to drug pricing; state and local laws requiring the registration of pharmaceutical sales representatives; and state 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; and

- The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products.

The failure to comply with any of these laws or regulatory requirements subjects companies to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, possible exclusion from participation in federal and state funded healthcare programs, contractual damages and the curtailment or restricting of our operations, as well as additional reporting obligations and oversight if a company becomes subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. Any action for violation of these laws, even if successfully defended, could cause a pharmaceutical company to incur significant legal expenses and divert management's attention from the operation of the business.

Health Reform

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the ACA was passed, which substantially changed the way healthcare is financed by both governmental and private insurers, and continues to significantly impact the U.S. pharmaceutical industry.

Since its enactment, there have been judicial, congressional and executive challenges to the ACA. In addition, there have been a number of health reform initiatives by the Biden administration that have impacted the ACA. For example, on August 16, 2022, President Biden signed the the Inflation Reduction Act (the IRA) into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost through a newly established manufacturer discount program. It is unclear how the healthcare reform initiatives of the Biden administration or other efforts, if any, to challenge, repeal or replace the ACA will impact the pharmaceutical industry and our business.

Additionally, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. presidential executive orders, congressional inquiries and proposed and enacted 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. For example, in July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, the U.S. Department of Health and Human Services (HHS) released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. In addition, the IRA, among other things, (1) directs HHS to negotiate the price of certain single-source drugs and biologics covered under Medicare and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions take effect progressively starting in fiscal year 2023, although they may be subject to legal challenges. Further, the Biden administration released an additional executive order on October 14, 2022, directing HHS to submit a report on how the Center for Medicare and Medicaid Innovation can be further leveraged to test new models for lowering drug costs for Medicare and Medicaid beneficiaries.

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. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for a particular product or put pressure on product pricing, which could negatively affect a company's business, financial condition, results of operations and prospects.

Coverage and Reimbursement

Sales of our products, when and if approved, will depend, in part, on the extent to which our products will be covered by third-party payors, such as federal, state, and foreign government health programs, commercial insurance and managed healthcare organizations. In the United States, no uniform policy of coverage and reimbursement for drug or biological products exists, and coverage and reimbursement can differ significantly from payor to payor. Accordingly, decisions for any of our products, if approved, will be made on a payor-by-payor basis, and factors payors consider in determining the extent of coverage and amount of reimbursement are based on whether the 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.
- In the United States, for example, principal decisions about reimbursement for new products are typically made by CMS, which decides whether and to what extent a new product will be covered and reimbursed under Medicare. Private third-party payors often follow CMS's decisions regarding coverage and reimbursement to a substantial degree. However, one third-party payor's determination to provide coverage for a product does not assure that other payors will also provide coverage for the product As a result, coverage determination is often a time-consuming and costly process that will require a company to provide scientific and clinical support for the use of its products to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained.

The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost containment programs to limit the growth of government-paid health care costs, including price-controls, restrictions on reimbursement and requirements for substitution of biosimilars for branded prescription drugs. Adoption of general controls and measures, coupled with the tightening of restrictive policies in jurisdictions with existing controls and measures, could limit payments for pharmaceutical drugs.

Assuming coverage is obtained for a given product by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. Further, coverage policies and third-party payor reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained, less favorable coverage policies and reimbursement rates may be implemented in the future. Patients who are prescribed medications for the treatment of their conditions, and their prescribing physicians, generally rely on third-party payors to reimburse all or part of the costs associated with their prescription drugs. Patients are unlikely to use products unless coverage is provided and reimbursement is adequate to cover all or a significant portion of the cost of prescribed products.

In addition, in most foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing and reimbursement vary widely from country to country. For example, the EU provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Historically, products launched in the EU do not follow price structures of the United States and generally prices tend to be substantially lower.

Competition

The biopharma industry is characterized by intense competition and rapid innovation. Our potential competitors include large pharmaceutical and biotechnology companies, specialty pharmaceutical companies and generic drug companies. Many of our potential competitors have greater financial and technical human resources than we do, as well as equal or greater experience in the discovery and development of product candidates, obtaining FDA and other regulatory approvals of products, and the commercialization of those products. Accordingly, our potential competitors may be more successful than us in achieving regulatory approvals and commercializing their drugs. We anticipate that we will face intense and increasing competition from existing, approved drugs, as well as new drugs entering the market and emerging technologies that become available. Finally, the development of new treatment methods for the diseases we are targeting could render our product candidates non-competitive or obsolete.

We believe the key competitive factors that will affect the development and commercial success of our product candidates, if approved, will be efficacy, safety, tolerability profile, convenience of dosing, price, and coverage by governmental and third-party payors.

We are currently developing izokibep for the treatment of HS, PsA, AxSpA and uveitis. Many emerging and established life sciences companies have been focused on similar therapeutics. If approved, izokibep would compete with several currently approved therapeutics, including Cosentyx (marketed by Novartis AG), Taltz (marketed by Eli Lily and Company), Humira (marketed by AbbVie Inc.), Remicade (marketed by Johnson & Johnson, Inc.), Enbrel (marketed by Immunex Corporation, a wholly owned subsidiary of Amgen Inc.), Cimzia (marketed by UCB Group of Companies), Simponi (marketed by Janssen Biotech, Inc.), Tremfya (marketed by Janssen Pharmaceutical Companies of Johnson & Johnson, Inc.), Xeljanz (marketed by Pfizer Inc.), Otezla (marketed by Amgen Inc.) and Orencia (marketed by Bristol-Myers Squibb Company). Izokibep would also compete with generic drugs, such as biosimilar versions of Humira and Cosentyx, including biosimilars marketed by Amgen, Pfizer and others recently approved, as well as several others we anticipate will receive approvals in the near term. There are also a number of product candidates in clinical development by third parties that are intended to treat HS, PsA, AxSpA and uveitis, including DC-806, being developed by DICE Therapeutics, Inc., sonelokimab, being developed by MoonLake Immunotherapeutics AG, povorcitinib, being developed by Incyte Corporation and zunsemetinib, being developed by Aclaris Therapeutics, Inc.

We are also developing lonigutamab for the treatment of TED. Tepezza, marketed by Horizon Therapeutics Public Ltd Co, is the only approved product for use in the treatment of TED in the United States. In addition to Tepezza, other therapies, such as corticosteroids, have been used on an off-label basis to alleviate some of the symptoms of TED. While these other therapies have not proved effective in treating the underlying disease, and carry with them significant side effects, their off-label use could reduce or delay treatment in the addressable patient population for lonigutamab. There are also a number of product candidates in clinical development by third parties that are intended to treat TED, including for instance batoclimab, being developed by Immunovant, Inc., VRDN-001, being developed by Viridian Therapeutics, Inc. and linsitinib, being developed by Sling Therapeutics, Inc.

In addition to our clinical-stage programs, we are also developing XLRN-517, a preclinical stage anti-c-KIT product candidate, which we are developing for the treatment of chronic urticaria and potentially other mast cell-driven disease indications. Xolair, marketed by Novartis, is the only approved product for use in the treatment of chronic urticaria in the United States. We are aware of competitive, approved therapeutics for other mast cell driven diseases including Fasenra (marketed by AstraZeneca PLC) and Dupixent (marketed by Sanofi S.A.). There are also a number of product candidates in clinical development by third parties for the treatment of chronic urticaria and other mast cell driven diseases, including barzolvolimab, being developed by Celldex Therapeutics, Inc., nemolizumab, being developed by Chugai Pharmaceutical, fenebrutinib, being developed by Genentech, Inc., ligelizumab, being developed by Novartis, and nalbuphine, being developed by Pfizer.

Employees and Human Capital Resources

As of December 31, 2022, we had 47 full-time employees, consisting of clinical, scientific, development, technical operations, regulatory, finance, and operational personnel. None of our employees is subject to a collective bargaining agreement. We consider our relationship with our employees to be good.

We recognize that our continued ability to attract, retain, and motivate exceptional employees is vital to ensuring our long-term competitive advantage. Our employees are critical to our long-term success and are essential to helping us meet our goals. Among other things, we support and incentivize our employees in the following ways:

- Talent development, compensation, and retention: Our human capital resources 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.
- Health and safety: We support the health and safety of our employees by providing comprehensive insurance benefits, an employee assistance program, company-paid holidays, a personal time-off program, and other additional benefits which are intended to assist employees to manage their well-being.
- Inclusion and diversity: We are committed to efforts to increase diversity and foster an inclusive work environment that supports our workforce.

Facilities

On January 6, 2023, we entered into an agreement to lease approximately 10,000 square feet of office space located in Agoura Hills, California. The term of the lease is 65 months with an option to extend the term by an additional three-year period. We believe our facilities are adequate and suitable for our current needs and that should it be needed, suitable additional or alternative space will be available to accommodate our operations.

Legal Proceedings

From time to time, we may become involved in material legal proceedings or be subject to claims arising in the ordinary course of our business. We are currently not party to any legal proceedings material to our operations or of which any of our property is the subject, nor are we aware of any such proceedings that are contemplated by a government authority. Regardless of outcome, such proceedings or claims can have an adverse impact on us because of defense and settlement costs, diversion of resources, and other factors, and there can be no assurances that favorable outcomes will be obtained.

MANAGEMENT

Executive Officers and Directors

The following table sets forth information regarding our executive officers and directors as of January 31, 2023.

Name	Age	Position(s)
Executive Officers:		
Shao-Lee Lin, M.D., Ph.D.	56	Founder, Chief Executive Officer and Director
Mardi C. Dier	58	Chief Financial Officer and Chief Business Officer
Melanie Gloria	45	Chief Operating Officer
Mina Kim	48	Chief Legal and Administrative Officer
Ron Oyston	53	Chief People Officer
Paul M. Peloso, M.D.	65	Chief Medical Officer
Non-Employee Directors:		
Bruce C. Cozadd	59	Chair and Director
Dan Becker, M.D., Ph.D.	47	Director
Alan Colowick, M.D., M.P.H.	60	Director
Patrick Machado, J.D.	58	Director
Beth Seidenberg M.D.	65	Director
Dawn Svoronos	69	Director

(1) Member of the compensation committee.
(2) Member of the nominating and corporate governance committee.
(3) Member of the audit committee.

Executive Officers

Shao-Lee Lin, M.D., Ph.D. is our Founder, Chief Executive Officer and a member of our board of directors since July 2020. She currently serves as a director of Surrozen, Inc. since January 2021, which is a publicly-traded company, and previously served as a director of Third Harmonic Bio, Inc., a publicly traded company, from September 2020 to January 2023 and Principia Biopharma Inc., a publicly traded company, from April 2019 to September 2020. She is also a trustee of the board of Lake Forest College. From January 2018 to January 2020, Dr. Lin served as the Executive Vice President, Head of Research and Development, and Chief Scientific Officer at Horizon Therapeutics Public Limited Company, which is a biopharmaceutical company. Prior to that, she held multiple positions including at the corporate officer level within AbbVie Inc., which is a biotechnology company, most recently leading Therapeutic Areas, Development Excellence and International Development and initially as Vice President, Global Immunology and Renal Development from March 2015 to December 2017. Prior to AbbVie, Dr. Lin served as Vice President, Inflammation and Respiratory Development at Gilead Sciences Inc. from August 2012 to February 2015 and served in various roles of increasing responsibility at Amgen Inc. from April 2004 to August 2012. Dr. Lin has been faculty as a Clinical Scholar at The Rockefeller University and adjunct faculty at the medical schools of Cornell University, The University of California, Los Angeles (UCLA), Stanford University and Northwestern University. Dr. Lin received an M.D. and Ph.D. from The Johns Hopkins University School of Medicine as a part of the National Institutes of Health-sponsored medical scientist training program and a bachelor's degree in chemical engineering and biochemistry from Rice University. We believe that Dr. Lin's scientific and medical expertise, as well as her industry, academic and leadership roles, make her an appropriate member of our board of directors.

Mardi C. Dier has served as our Chief Financial Officer and Chief Business Officer since November 2022. She currently serves as a director of Synthekine Inc. since May 2021, as a director of Prelude Therapeutics Incorporated, a publicly-traded company, since August 2020 and as a director of ORIC Pharmaceuticals, Inc., a publicly-traded company, since February 2020. Ms. Dier previously served as a director of Adamas Pharmaceuticals, Inc. from August 2017 to May 2021. From October 2020 to November 2022, Ms. Dier was the Chief Financial Officer of Ultragenyx Pharmaceutical Inc., which is a biopharmaceutical company. Prior to that, Ms. Dier served in various positions at Portola Pharmaceuticals, a pharmaceutical company, including as Executive Vice President, Chief Financial Officer and Chief Business Officer from August 2006 to July 2020 through its acquisition by Alexion Pharmaceuticals. Prior to her time at Portola, she served as Vice President of Investor Relations at Chiron Corporation from January 2003 to May 2006 until its acquisition by Novartis, AG. From March 1994 to June 2001, she was in the banking group at Prudential Securities, Inc. covering biopharma, and prior to that was in the audit department of KPMG Peat Marwick. Since May 2022, Ms. Dier has served as a member of the board of advisors of the UCLA Anderson School of Management. She received a B.S. in biology from Stanford University and a M.B.A. from the Anderson School at UCLA.

Melanie Gloria has served as our Chief Operating Officer since November 2021. From June 2018 to November 2021, she was the Senior Vice President Development Operations – ClinOps, Compliance & Standards, Regulatory, Safety & PV at Horizon Therapeutics Public Limited Company. From August 2014 through July 2018, Ms. Gloria served as Senior Director of Clinical Program Development at AbbVie Inc. From November 2009 to August 2014, she was Associate Director of Clinical Program Development for Abbott Laboratories. Ms. Gloria received a B.S. in nursing from the University of Illinois, Chicago.

Mina Kim has served as our Chief Legal and Administrative Officer since November 2022. From January 2020 to September 2022, she served as Chief Legal Officer and Head of Corporate Development at Zymergen, Inc., a biotechnology company. Previously, she also served as the Senior Vice President of Corporate Strategy and General Counsel of Atara Biotherapeutics, Inc., a pharmaceutical company, from April 2018 to November 2019. From March 2014 to April 2018, Ms. Kim was the General Counsel of Sunrun Inc., a residential solar energy company, and from September 2007 to March 2014, Ms. Kim was Vice President, Legal for BBAM, LLC. Ms. Kim received a J.D. from Harvard Law School and a B.A. in History from Dartmouth College.

Ron Oyston has served as our Chief People Officer since September 2022. From November 2021 to September 2022, he served as our Senior Vice President and Head of Human Resources. From June 2018 to October 2021, Mr. Oyston held various positions at Horizon Therapeutics plc, including Vice President of HR. Previously, he served as Senior Global Director of Human Resources and Director of Human Resources for Kerry Group plc, a food manufacturing company, from August 2016 to June 2018, Global Director of Human Resources and Director of Human Resources for AbbVie Inc. from January 2013 to July 2016, and as Regional Development Manager and Director of Consulting for Abbott Laboratories between September 2008 to December 2012. Mr. Oyston also worked as a Talent & Business Senior Manager for The Emirates Group between June 2006 to August 2008, and as a Technical Partner for the Royal Bank of Scotland plc from July 2001 to July 2006. Mr. Oyston received a M.B.A. from the University of Edinburgh and holds various qualifications from the Chartered Institute of Personal Development, Chartered Insurance Institute, and the Chartered Institute of Banking covering his experiences in Human Resources and Finance.

Paul M. Peloso, M.D., M.Sc. has served as our Chief Medical Officer since May 2021. From May 2018 to May 2021, he was the Vice President and Therapeutic Area Head, Rheumatology at Horizon Therapeutics Public Limited Company. From December 2013 through May 2018, Dr. Peloso served as the Group Medical Director-Clinical Development at AbbVie Inc. Prior to that, he was the Executive Director of Clinical Research for Merck & Co. Inc. from November 2006 to November 2013. Dr. Peloso received a B.Sc. in chemistry and a B.A. in sociology from McMaster University. In addition, Dr. Peloso received his M.D. from the University of Calgary, and his M.Sc. in clinical epidemiology from the University of Toronto.

Non-Employee Directors

Bruce C. Cozadd has served as a member of our board of directors since March 2022. In January 2023, Mr. Cozadd assumed the role of chair of our board of directors. Mr. Cozadd co-founded Jazz Pharmaceuticals plc and has served as Chairperson and Chief Executive Officer of Jazz Pharmaceuticals plc since April 2009 and from October 2019 through March 2020, he served as the interim principal financial officer of Jazz Pharmaceuticals plc. From 1991 until 2001, he held various positions with ALZA Corporation, a pharmaceutical company acquired by Johnson & Johnson, most recently as Executive Vice President and Chief Operating Officer, with responsibility for research and development, manufacturing and sales and marketing. Previously at ALZA Corporation, he held the roles of Chief Financial Officer and Vice President, Corporate Planning and Analysis. Mr. Cozadd also serves on the board of Biotechnology Innovation Organization, a biotechnology trade association, where he serves on its Health Section Governing Board. He also serves on the boards of two non-profit organizations, The Nueva School and SFJAZZ. Mr. Cozadd previously served on the boards of directors of Cerus Corporation from 2001 to January 2018 and Threshold Pharmaceuticals, Inc. from 2005 to August 2017. He received a B.S. in molecular biophysics & biochemistry and economics from Yale University and an M.B.A. from the Stanford Graduate School of Business. We believe that Mr. Cozadd's education and extensive experience in research and development, manufacturing and sales and marketing makes him an appropriate member of our board of directors.

Dan Becker, M.D., Ph.D. has served as a member of our board of directors since September 2022. He currently serves as a Managing Director at Access Biotechnology, the biopharmaceutical investing arm of Access Industries, a privately held US-based industrial group, since August 2019. Previously, Dr. Becker served as a Principal at New Leaf Venture Partners, a venture capital firm, from January 2015 to May 2019, and a Principal in the Health Care practice at the Boston Consulting Group, from August 2009 to January 2015. Dr. Becker trained clinically in internal medicine and nephrology at Brigham and Women's Hospital and Massachusetts General Hospital, and was a Research Fellow at Harvard Medical School. Since December 2019, Dr. Becker has served on the board of directors of Day One Biopharmaceuticals, Inc. Previously, Dr. Becker served on the boards of directors of Principia Biopharma Inc., a publicly traded company, from January 2017 to September 2020 and Pandion Therapeutics, Inc. from March 2020 to March 2021. He obtained both his M.D. and Ph.D. (Cellular and Molecular Biology) degrees from the University of Michigan, and received his B.S. in Physiology from the University of Illinois at Urbana-Champaign. We believe that Dr. Becker is qualified to serve on our board of directors because of his medical training and expertise in early stage biotech companies.

Alan Colowick, M.D., M.P.H. has served as a member of our board of directors since November 2021. Dr. Colowick has served a managing director at Matrix Capital Management Company, L.P., an investment management firm, since April 2021. From May 2017 to January 2021, Dr. Colowick served as a Partner at Sofinnova Investment, Inc., a clinical stage life sciences venture capital firm. Prior to that, Dr. Colowick held various positions, including Executive Vice President, at Celgene Corporation, a pharmaceutical company, from February 2010 to April 2017. Dr. Colowick served as the Chief Executive Officer of Gloucester Pharmaceuticals Inc., an early-stage cancer pharmaceutical company, from February 2008 until its acquisition by Celgene Corporation in January 2010. From October 2006 to February 2008, Dr. Colowick served as President, Oncology at Geron Corporation (Nasdaq: GERN), a pharmaceutical company. Earlier in his career, Dr. Colowick served as Chief Medical Officer at Threshold Pharmaceuticals Inc., a biotechnology company, and served in various capacities at Amgen Inc. (Nasdaq: AMGN), a biopharmaceutical company. Dr. Colowick currently serves on the board of directors of ReCode Therapeutics, Inc. since June 2022, Alumis Inc. since January 2022, AC Immune SA (Nasdaq: ACIU) since March 2021, Personalis, Inc. (Nasdaq: PSNL) since May 2019, Harpoon Therapeutics, Inc. since March 2021, XyloCor Therapeutics, Inc. since October 2018, and InCarda Therapeutics, Inc. since October 2017. He previously served as executive chair and chair of the board of directors of Principia Biopharma Inc. (acquired by Sanofi in September 2020) from February 2017 to September 2020, the chairman of the board of directors of VelosBio Inc. from September 2018 to December 2020, and a director of Human Longevity, Inc. from June 2016 to June 2019. Dr. Colowick holds an M.D. from Stanford University School of Medicine, an M.P.H. from the Harvard School of Public Health, and a B.S. in Molecular Biology from the University of

Colorado. We believe that Dr. Colowick's extensive professional experience, as well as financial understanding of the biotechnology industry, provide him with the qualifications and skills to serve on our board of directors.

Patrick Machado, J.D. has served as a member of our board of directors since May 2021. Mr. Machado was a co-founder of Medivation, Inc., a biopharmaceutical company, and served as its chief business officer from December 2009 to April 2014 and as its chief financial officer from December 2004 until his retirement in March 2014. From 1998 to 2001, Mr. Machado worked with ProDuct Health, Inc., a medical device company, as senior vice president, chief financial officer and earlier as general counsel. Upon ProDuct Health Inc.'s acquisition by Cytyc Corporation, a diagnostic and medical device company, he served as a consultant to Cytyc Corporation to assist with transitional matters from 2001 to 2002. Earlier in his career, Mr. Machado worked for Morrison & Foerster LLP, an international law firm, and for the Massachusetts Supreme Judicial Court. Mr. Machado also serves as chair of the board of directors of Adverum Biotechnologies, Inc., a publicly traded company, since March 2017 and as a member of the board of directors of Arcus Biosciences, Inc., a publicly traded company, since December 2019, Chimerix, Inc., a publicly traded company, since June 2014, Xenon Pharmaceuticals, Inc., a publicly traded company, since November 2020, and Turnstone Biologics Inc. since August 2018. Mr. Machado previously served on the board of directors of public traded companies such as Turning Point Therapeutics, Inc. from May 2019 to September 2022, Endocyte, Inc. from February 2018 to December 2018, Axovant Sciences, Inc. from June 2017 to February 2018, SCYNEXIS, Inc. from September 2015 to June 2019, Medivation, Inc. from April 2014 to September 2016; and on the board of directors of privately held companies such as Inotek Pharmaceuticals Corporation (now Rocket Pharmaceuticals, Inc.) from August 2016 to January 2018, Roivant Sciences, Ltd. from October 2016 to June 2022, Principia Biopharma Inc. from June 2019 to September 2020, and Therachon AG from January 2019 to July 2019. He received a J.D. from Harvard Law School and a B.A. in German and a B.S. in Economics from Santa Clara University. We believe that Mr. Machado's extensive experience dealing with the operational and financial issues of biopharmaceutical companies provide him with the qualifications and skills to serve on our board of directors.

Beth Seidenberg, M.D. has served as a member of our board of directors since October 2020. Dr. Seidenberg is the managing director of Westlake Village BioPartners, a venture capital firm that focuses on life sciences that she founded in September 2018. Dr. Seidenberg is also a General Partner at Kleiner Perkins Caufield & Byers, a venture capital firm, where she has primarily focused on life sciences investing since May 2005. Dr. Seidenberg was previously the Senior Vice President, Global Development and Chief Medical Officer at Amgen, Inc., a biotechnology company from 2002 to 2005. In addition, Dr. Seidenberg was a senior executive in research and development at Bristol Myers Squibb Company, a biopharmaceutical company, from March 2000 to January 2022 and held various roles at Merck & Co. Inc. from June 1989 to February 2000, including as a senior executive in research and development. Dr. Seidenberg has served on the board of directors of publicly traded companies, including Progyny, Inc., since May 2010, Atara Biotherapeutics, Inc. since August 2012, and Vera Therapeutics, Inc. since June 2016. Dr. Seidenberg formerly served on the board of directors of TESARO, Inc., a publicly traded company, from June 2011 to February 2018, RAPT Therapeutics, Inc, from April 2015 to June 2019, ARMO BioScience Inc. from December 2012 to June 2018, and Epizyme, Inc. from February 2008 to September 2019. Dr. Seidenberg holds a B.S. from Barnard College and an M.D. from the University of Miami School of Medicine and completed her post-graduate training at The Johns Hopkins University, George Washington University and the National Institutes of Health. We believe that Dr. Seidenberg is qualified to serve on our board of directors due to her extensive experience in the life sciences industry as a senior executive and venture capitalist, as well as her training as a physician.

Dawn Svoronos has served as a member of our board of directors since December 2022. Ms. Svoronos sits on the board of directors of several publicly-traded biopharmaceutical companies, including Adverum Biotechnologies since December 2020, Xenon Pharmaceuticals Inc. since September 2016, and Theratechnologies Inc. since May 2013, where she is currently the chair of its board of directors. Since January 2015, she has served as a director of AgNovos Healthcare LLC. Ms. Svoronos previously served as a director of PTC Therapeutics, Inc. from June 2016 to December 2022, Global Blood Therapeutics, Inc. from December 2018 to October 2022, Endocyte, Inc. from May 2018 to December 2018, and Medivation Inc. from April 2013

to September 2016. Ms. Svoronos retired in 2011 from Merck & Co., Inc. following a 23-year career in commercial positions of increasing seniority, most recently as President of Europe and Canada. Her previously held positions with Merck include Vice President of Asia Pacific and Vice President of Global Marketing for the Arthritis, Analgesics and Osteoporosis franchise. Ms. Svoronos received a B.A. in English and French Literature from Carleton University. We believe that Ms. Svoronos is qualified to serve as a director because of her experience in commercialization of pharmaceutical products and her senior management experience in the pharmaceutical industry.

Composition of Our Board of Directors

Our business and affairs are organized under the direction of our board of directors, which currently consists of seven members with no vacancies. The primary responsibilities of our board of directors are to provide oversight, strategic guidance, counseling and direction to our management. Our board of directors meets on a regular basis and additionally as required.

Certain members of our board of directors were elected under the provisions of our Amended and Restated Voting Agreement entered into in September 2022 (the Voting Agreement), which will terminate upon the closing of this offering. Under the terms of our Voting Agreement, the stockholders who are party to the Voting Agreement have agreed to vote their respective shares to elect: (i) one director designated by Westlake BioPartners Fund II, L.P., currently Beth Seidenberg; (ii) one director designated by AyurMaya Capital Management Fund, L.P. (Matrix), currently Alan Colowick; (iii) one director designated by AI ACEL LLC, currently Dan Becker; (iv) our Chief Executive Officer, Shao-Lee Lin, M.D., Ph.D.; (v) three directors who are industry representatives, not otherwise our affiliate or employee or of any of our investors, and mutually acceptable to the other members of the board of directors, currently Dawn Svoronos, Patrick Machado and our Chair, Bruce Cozadd. The Voting Agreement will terminate upon the closing of this offering, at which point no stockholder will have any special rights regarding the election or designation of the members of our board of directors. Our current directors elected to our board of directors pursuant to the Voting Agreement will continue to serve as directors until a successor is duly elected and qualified, or until his or her earlier resignation or removal.

Our board of directors may establish the authorized number of directors from time to time by resolution. In accordance with our amended and restated certificate of incorporation to be filed in connection with this offering, immediately after this offering, our board of directors will be divided into three classes with staggered three-year terms. At each annual meeting of stockholders, the successors to directors whose terms then expire will be elected to serve from the time of election and qualification until the third annual meeting following election. Our directors will be divided among the three classes as follows:

- the Class I directors will be , and , and their terms will expire at the annual meeting of stockholders to be held in 2024;
- the Class II directors will be and , and their terms will expire at the annual meeting of stockholders to be held in 2025; and
- the Class III directors will be and , and their terms will expire at the annual meeting of stockholders to be held in 2026.

The division of our board of directors into three classes with staggered three-year terms may delay or prevent a change of our management or a change in control.

Director Independence

Under the Nasdaq Listing Rules independent directors must comprise a majority of our board of directors as a listed company within one year of the listing date.

Our board of directors has undertaken a review of the independence of each director. Based on information provided by each director concerning her or his background, employment and affiliations, including family relationships, our board of directors has determined that none of our directors, other than Dr. Lin, has any 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 Nasdaq Listing Rules. Our board of directors has determined that Dr. Lin, by virtue of her position as our Chief Executive Officer, is not independent under applicable rules and regulations of the SEC and the Nasdaq Listing Rules. 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 shares by each non-employee director and the transactions described in the section titled "Certain Relationships and Related Person Transactions."

Committees of Our Board of Directors

Our board of directors has established an audit committee, a compensation committee and a nominating and corporate governance committee. The composition and responsibilities of each of the committees of our board of directors are described below. Members serve on these committees until their resignation or until otherwise determined by our board of directors. Each committee intends to adopt a written charter that satisfies the application rules and regulation of the SEC and the Nasdaq Listing Rules, which we will post to our website at www.acelyrin.com upon the closing of this offering. Our board of directors may establish other committees as it deems necessary or appropriate from time to time. Information contained on, or accessible through, our website is not a part of this prospectus, and the inclusion of our website address in this prospectus is only an inactive textual reference.

Audit Committee

Our audit committee currently consists of , and , each of whom our board of directors has determined satisfies the independence requirements under the Nasdaq Listing Rules and Rule 10A-3(b)(1) of the Securities Exchange Act of 1934, as amended (Exchange Act). The chair of our audit committee is , who our board of directors has determined is an "audit committee financial expert" within the meaning of SEC regulations. Each member of our audit committee can read and understand fundamental financial statements in accordance with applicable requirements. In arriving at these determinations, the board of directors has examined each audit committee member's scope of experience and the nature of their employment in the corporate finance sector.

The primary purpose of the audit committee is to discharge the responsibilities of our board of directors with respect to our corporate accounting and financial reporting processes, systems of internal control and financial-statement audits, and to oversee our independent registered accounting firm. Specific responsibilities of our audit committee include:

- helping our board of directors oversee our corporate accounting and financial reporting processes;
- managing the selection, engagement, qualifications, independence and performance of a qualified firm to serve as the independent registered public accounting firm to audit our financial statements;
- discussing the scope and results of the audit with the independent registered public accounting firm, and reviewing, with management and the independent accountants, our interim and year-end operating results;
- developing procedures for employees to submit concerns anonymously about questionable accounting or audit matters;
- reviewing and overseeing related person transactions;

- obtaining and reviewing a report by the independent registered public accounting firm at least annually, that describes our internal quality control procedures, any material issues with such procedures, and any steps taken to deal with such issues when required by applicable law; and
- approving, or, as permitted, pre-approving, audit and permissible non-audit services to be performed by the independent registered public accounting firm.

Compensation Committee

Our compensation committee currently consists of , and . The chair of our compensation committee is . Our board of directors has determined that each member of our compensation committee is independent under the Nasdaq Listing Rules.

The primary purpose of our compensation committee is to discharge the responsibilities of our board of directors in overseeing our compensation policies, plans and programs and to review and determine the compensation to be paid to our executive officers and directors. Specific responsibilities of our compensation committee include:

- reviewing and approving the compensation of our chief executive officer and other executive officers;
- reviewing and recommending to our board of directors the compensation paid to our directors;
- administering our equity incentive plans and other benefit programs;
- reviewing, adopting, amending and terminating, incentive compensation and equity plans, severance agreements, profit sharing plans, bonus plans, change-of-control protections and any other compensatory arrangements for our executive officers;
- reviewing, evaluating and recommending to our board of directors succession plans for our executive officers; and
- reviewing and establishing general policies relating to compensation and benefits of our employees, including our overall compensation strategy, including base salary, incentive compensation and equity-based grants, to assure that they promote stockholder interests and support our strategic objectives, and that they provide for appropriate rewards and incentives for our management and employees.

Nominating and Corporate Governance Committee

Our nominating and corporate governance committee consists of , and . The chair of our nominating and corporate governance committee is . Our board of directors has determined that each member of the nominating and corporate governance committee is independent under the Nasdaq Listing Rules.

Specific responsibilities of our nominating and corporate governance committee include:

- identifying and evaluating candidates, including the nomination of incumbent directors for reelection and nominees recommended by stockholders, to serve on our board of directors;
- considering and making recommendations to our board of directors regarding the composition and chairmanship of the committees of our board of directors;
- instituting plans or programs for the continuing education of our board of directors and orientation of new directors;
- developing and making recommendations to our board of directors regarding corporate governance guidelines and matters; and
- overseeing periodic evaluations of the board of directors' performance.

Code of Business Conduct and Ethics

In connection with this offering, we intend to adopt a written Code of Business Conduct and Ethics that applies to all our employees, officers and directors. This includes our principal executive officer, principal financial officer and principal accounting officer or controller, or persons performing similar functions. The full text of our Code of Business Conduct and Ethics will be posted on our website at www.acelyrin.com upon the closing of this offering. We intend to disclose on our website any future amendments of our Code of Business Conduct and Ethics or waivers that exempt any principal executive officer, principal financial officer, principal accounting officer or controller, persons performing similar functions or our directors from provisions in the Code of Business Conduct and Ethics.

Compensation Committee Interlocks and Insider Participation

None of the members of the compensation committee is currently, or has been at any time, one of our executive officers or employees. None of our executive officers currently serves, or has served during the last completed fiscal year, as a member of the board of directors or compensation committee of any entity that has one or more executive officers serving as a member of our board of directors or compensation committee.

Non-Employee Director Compensation

The following table presents the compensation awarded to or earned by or paid to all individuals who served as non-employee directors during the year ended December 31, 2022.

Name	Fees Earned or Paid in Cash ($)	Option Awards ($)[1][2]	Total ($)
Bruce C. Cozadd[3]	42,407	594,271	636,678
Dan Becker, M.D., Ph.D.[4]	—	—	—
Alan Colowick, M.D., M.P.H.	—	—	—
Richard Gaster, M.D., Ph.D.[5]	—	—	—
Sean Harper, M.D.[6]	—	—	—
Patrick Machado J.D.	34,000	656,607	690,607
Beth Seidenberg, M.D.	—	—	—
Dawn Svoronos[7]	2,833	731,823	734,656

(1) Amounts reflect the full grant-date fair value of stock options granted during 2022 computed in accordance with Financial Accounting Standards Board (FASB) Accounting Standard Codification (ASC) Topic 718, rather than the amounts paid to or realized by the non-employee director. See Notes 2 and 7 to our financial statements included elsewhere in this prospectus for a discussion of the assumptions used in the calculation.
(2) As of December 31, 2022, the aggregate number of shares underlying outstanding options to purchase shares of our Class A Common Stock held by our non-employee directors were: Mr. Cozadd, 361,732; Mr. Machado, 306,549; and Ms. Svoronos, 306,549. None of our other non-employee directors held options to purchase shares of our Class A Common Stock as of December 31, 2022. None of our non-employee directors held other unvested stock awards as of December 31, 2022.
(3) Mr. Cozadd joined our board of directors on March 7, 2022.
(4) Dr. Becker joined our board of directors on September 9, 2022.
(5) Dr. Gaster resigned from our board of directors on December 1, 2022.
(6) Dr. Harper resigned from our board of directors on October 21, 2022.
(7) Ms. Svoronos joined our board of directors on December 1, 2022.

Drs. Becker, Colowick, Gaster, Harper and Seidenberg were not compensated for their service on our board of directors during the year ended December 31, 2022. Dr. Lin also served on our board of directors during the year ended December 31, 2022, but did not receive any additional compensation for her service as a director. See the section titled “Executive Compensation” for more information regarding the compensation earned by Dr. Lin. The above table also does not include Robert Carey, who served as a member of our board of directors until his resignation on April 18, 2022. During his term of office as a director, Mr. Carey also served as an executive officer (and is not a named executive officer) and did not receive any additional compensation for his service as a director.

Pursuant to our current compensation arrangements, Mr. Cozadd was entitled to an annual stipend of $50,000 for his board service and each of Mr. Machado and Ms. Svoronos are entitled to an annual stipend of $34,000, prorated for their respective terms of service, paid on a quarterly basis. In addition, in March 2022, Mr. Cozadd was granted an option to purchase 361,732 shares of our Class A Common Stock, with an exercise price of $2.05 per share, that vests in 48 equal monthly installments subject to Mr. Cozadd's continued service with us. In July 2021, Mr. Machado was granted an option to purchase 80,000 shares of our Class A Common Stock with an exercise price of $0.3896 per share, that vests in 48 equal monthly installments subject to Mr. Machado's continued service with us. In November 2022, Mr. Machado was granted an additional option to purchase 226,549 shares of our Class A Common Stock, with an exercise price of $2.98 per share, that vests in 48 equal monthly installments subject to Mr. Machado's continued service with us. In December 2022, Ms. Svoronos was granted an option to purchase 306,549 shares of our Class A Common Stock with an exercise price of $2.98 per share, that vests in 48 equal monthly installments subject to Ms. Svoronos' continued service with us.

Outstanding equity awards held by our non-employee directors are subject to the terms of our 2020 Plan, as described in the section titled "Executive Compensation—Equity Benefit Plans—2020 Stock Option and Grant Plan."

We have reimbursed and will continue to reimburse all of our non-employee directors for their reasonable out-of-pocket expenses incurred in attending board of directors and committee meetings.

We intend to adopt a non-employee director compensation policy, pursuant to which our non-employee directors will be eligible to receive compensation for service on our board of directors and committees of our board of directors, to be effective following the completion of this offering.

EXECUTIVE COMPENSATION

Our named executive officers for the year ended December 31, 2022 were:

- Shao-Lee Lin, M.D., Ph.D., Founder, Chief Executive Officer and Director;
- Mardi C. Dier, Chief Financial Officer and Chief Business Officer; and
- Melanie Gloria, Chief Operating Officer.

Summary Compensation Table

The following table presents the compensation awarded to or earned by or paid to our named executive officers during the year ended December 31, 2022.

Name and Principal Position	Fiscal Year	Salary ($)	Stock Awards ($)[1]	Option Awards ($)[2]	Non-Equity Incentive Plan Compensation ($)[3]	All Other Compensation ($)	Total ($)
Shao-Lee Lin, M.D., Ph.D.							
Founder, Chief Executive Officer and Director	2022	516,375	1,305,130	—	329,871	—	2,151,376
Mardi C. Dier[4]							
Chief Financial Officer and Chief Business Officer	2022	64,394	—	3,198,592	28,623	—	3,291,609
Melanie Gloria							
Chief Operating Officer	2022	455,625	—	1,961,602	211,680	5,276[5]	2,634,183

(1) The amount reflects the grant-date fair value of vested stock awards for 636,649 shares of our Class A Common Stock, which were fully vested on the grant date. In addition, in March 2022 and November 2022, Dr. Lin was granted awards of 542,598 RSUs and 820,414 RSUs, respectively, which vest upon the satisfaction of both (i) a service-based vesting condition and (ii) a liquidity-based vesting condition. The liquidity-based vesting condition for such RSUs is the occurrence of a Liquidity Event, defined as the first to occur of: (a) a Sale Event (as defined in our 2020 Plan) (b) the completion of this offering or (c) the direct listing or direct placement of our equity securities in a publicly traded exchange. The service-based vesting condition will be satisfied as to 25% of the shares underlying the RSUs upon completion of one year of service measured from the vesting start date, and thereafter an additional 1/12th of the total number of shares underlying the RSUs will vest in quarterly installments, subject to continued service through each such vesting date. In November 2022, Dr. Lin was granted an additional award of 820,414 RSUs, which fully vests upon the occurrence of a Liquidity Event. Any unvested RSUs expire on the seven year anniversary of the grant date. In accordance with Financial Accounting Standards Board (FASB) Accounting Standard Codification (ASC) Topic 718, no grant date value was recognized for such RSUs because the Liquidity Event condition was not determined to be probable on the grant date. Assuming the Liquidity Event condition was met, the grant-date fair value of the RSUs granted to Dr. Lin would have been $6,001,993. All of the stock awards were granted under the 2020 Plan, the terms of which plan are described in the subsection titled "—Equity Benefit Plans—2020 Stock Option and Grant Plan."

(2) Amounts reflect the aggregate grant-date fair value of options awards granted during 2022 computed in accordance with FASB ASC Topic 718, rather than the actual economic value that may be realized by the named executive officer. See Notes 2 and 7 to our financial statements included elsewhere in this prospectus for a discussion of the assumptions used in the calculation. All of the option stock awards were granted under the 2020 Plan, the terms of which plan are described in the subsection titled "—Equity Benefit Plans—2020 Stock Option and Grant Plan" below.

(3) The amounts disclosed represent performance bonuses earned in 2022 and paid in February 2023. Ms. Dier's bonus was prorated to reflect her partial year of service. For more information, see the description of the annual performance bonuses in the subsection titled "—Narrative to the Summary Compensation Table—Annual Performance Bonus Opportunity" below.

(4) The amounts stated reflect the prorated portion of Ms. Dier's annual base salary from the commencement of her employment as our Chief Financial Officer and Chief Business Officer in November 2022. Ms. Dier's bonus was determined based on her prorated base salary for the year ended December 31, 2022.

(5) Amount shown represents 401(k) matching contributions.

Narrative to the Summary Compensation Table

Historically, our board of directors was responsible for overseeing all aspects of our executive compensation programs. In making compensation determinations, we consider compensation for comparable positions in the market, the historical compensation levels of our executives, individual performance as compared to our expectations and objectives, our desire to motivate our employees to achieve short- and long-term results that are in the best interests of our stockholders and a long-term commitment to our company.

Our board of directors has determined our executive officers' compensation and has typically reviewed and discussed management's proposed compensation with our chief executive officer for all executives other than our chief executive officer. Based on those discussions and its discretion, our board of directors then approved the compensation of each executive officer.

Annual Base Salary

Base salaries for our executive officers are initially established through arm's-length negotiations at the time of the executive officer's hiring, taking into account such executive officer's qualifications, experience, the scope of such executive officer's responsibilities and competitive market compensation paid by other companies for similar positions within the industry and geography. Base salaries are reviewed periodically, and adjusted from time to time to realign salaries with market levels after taking into account individual responsibilities, performance and experience.

The 2022 annual base salaries for our named executive officers are set forth in the table below.

Name	2022 Base Salary ($)
Shao-Lee Lin, M.D., Ph.D.(1)	535,500
Mardi C. Dier(2)	500,000
Melanie Gloria(3)	472,500

(1) Dr. Lin's base salary increased from $510,000 to $535,500, effective October 1, 2022.
(2) The amount stated in the Summary Compensation Table above reflects the prorated portion of Ms. Dier's annual base salary from the commencement of her employment as our Chief Financial Officer and Chief Business Officer in November 2022.
(3) Ms. Gloria's base salary increased from $450,000 to $472,500, effective October 1, 2022.

Annual Performance Bonus Opportunity

Our executive officers are eligible to earn an annual incentive bonus of up to a percentage of such executive officer's annual base salary, based on the achievement of pre-established performance objectives determined by our board of directors.

For 2022, each of Dr. Lin, Ms. Dier and Ms. Gloria was eligible to receive a target bonus equal to 55%, 40%, and 40% of their base salary, respectively, based on the achievement of certain corporate goals. In January 2023, our board of directors determined that the 2022 corporate goals were achieved at 112% overall, and as a result, approved annual performance bonuses for Dr. Lin, Ms. Dier and Ms. Gloria in the amounts of $329,871, $28,623 (determined based on her pro-rated base salary for 2022), and $211,680, respectively, as reflected in the "Non-Equity Incentive Plan Compensation" column of the Summary Compensation Table above.

Equity-Based Incentive Awards

Our equity award program is the primary vehicle for offering long-term incentives to our executive officers. We believe that equity awards provide our executives with a strong link to our long-term performance, create an ownership culture and help to align the interests of our executives and our stockholders. To date, we have used stock option grants, RSUs and restricted stock awards for this purpose because we believe they are an effective means by which to align the long-term interests of our executive officers with those of our stockholders. We

believe that our equity awards are an important retention tool for our executive officers, as well as for our other employees. Grants to our executive officers and other employees are made at the discretion of our board of directors and are not made at any specific time period during a year.

In March 2022, we granted Dr. Lin RSUs representing a contingent right to receive 542,598 shares of our Class A Common Stock. The RSUs include both a performance-based vesting requirement and a service-based vesting requirement. The performance-based requirement will be met upon the occurrence of a Liquidity Event, defined as the first to occur of: (i) immediately prior to a Sale Event (as defined in the 2020 Plan); (ii) the completion of our initial public offering; or (iii) the direct listing or direct placement of our equity securities in a publicly traded exchange. The performance-based requirement will be satisfied upon completion of this offering. The service-based requirement was satisfied with respect to 25% of the shares on January 1, 2023 and the balance of the service-based requirement will be satisfied thereafter in 12 equal quarterly installments, subject to Dr. Lin's continued service with us as of each such date. Any unvested RSUs expire on the seven year anniversary of the grant date. If Dr. Lin is terminated by the company without cause or resigns for good reason (each as defined in the Amended and Restated Stock Purchase Agreement by and between us and Dr. Lin, dated October 9, 2020, or the Lin SPA) within 12 months after a Sale Event (as defined in the 2020 Plan), the service-based requirement will be deemed satisfied in full. Additionally, in March 2022, we granted Dr. Lin a restricted stock award covering 636,649 shares of our Class A Common Stock. The restricted stock award had a price per share of $2.05 and was fully vested on the grant date.

In November 2022, we granted Dr. Lin RSUs representing a contingent right to receive 1,640,828 shares of our Class A Common Stock. 820,414 RSUs vest on the occurrence of a Liquidity Event, which will be satisfied upon the closing of this offering. The remaining 820,414 RSUs include both a performance-based vesting requirement and a service-based vesting requirement. The performance-based requirement will be met upon the occurrence of a Liquidity Event, which will be satisfied upon the closing of this offering. The service-based requirement was satisfied with respect to 25% of the shares on November 17, 2023 and the balance of the service-based requirement will be satisfied thereafter in 12 equal quarterly installments, subject to Dr. Lin's continued service with us as of each such date. Any unvested RSUs expire on the seven year anniversary of the grant date. If Dr. Lin is terminated by the company without cause or resigns for good reason (each as defined in the Lin SPA) within 12 months after a Sale Event (as defined in the 2020 Plan), the service-based requirement will be deemed satisfied in full.

In November 2022, in connection with her commencement of employment with us, we granted Ms. Dier an option to purchase 1,328,382 shares of our Class A Common Stock. The option has an exercise price of $2.98 per share and is subject to a four-year vesting schedule, with 25% of the shares vesting in November 2023 on the first anniversary of the vesting commencement date and the balance vesting monthly over 36 months thereafter, subject to Ms. Dier's continued service with us.

In January 2022, in connection with her commencement of employment with us, we granted Ms. Gloria an option to purchase 651,118 shares of our Class A Common Stock. The option has an exercise price of $2.05 per share and is subject to a four-year vesting schedule, with 25% of the shares vesting in November 2022 on the first anniversary of the vesting commencement date and the balance vesting monthly over 36 months thereafter, subject to Ms. Gloria's continued service with us. In November 2022, we granted Ms. Gloria an option to purchase 370,713 shares of our Class A Common Stock. The option has an exercise price of $2.98 per share and is subject to a four-year vesting schedule, with 25% of the shares vesting in November 2023 on the first anniversary of the vesting commencement date and the balance vesting monthly over 36 months thereafter, subject to Ms. Gloria's continued service with us.

Outstanding Equity Awards as of December 31, 2022

The following table presents the outstanding equity awards held by each named executive officer as of December 31, 2022.

	Option Awards[1]				Stock Awards[1]	
Name	Number of Securities Underlying Unexercised Options Exercisable (#)	Number of Securities Underlying Unexercised Options Unexercisable (#)	Option Exercise Price Per Share ($)	Option Expiration Date	Equity Incentive Plan Awards: Number of Unearned Shares, Units or Other Rights that Have Not Vested (#)	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Other Rights that Have Not Vested ($)[2]
Shao-Lee Lin, M.D., Ph.D.	—	—	—	—	1,050,000[3]	3,128,999
	—	—	—	—	542,598[4]	1,616,942
	—	—	—	—	820,414[5]	2,444,834
	—	—	—	—	820,414[6]	2,444,834
Mardi C. Dier	—	1,328,382[7]	2.9800	11/20/2032	—	—
Melanie Gloria	176,344	474,774[8]	2.0500	1/19/2032	—	—
	—	370,713[9]	2.9800	11/20/2032	—	—

(1) Except as set forth in footnote (3) below, all of the stock and option awards were granted under the 2020 Plan, the terms of which plan are described in the subsection titled "—Equity Benefit Plans—2020 Stock Option and Grant Plan" below.

(2) Amounts are calculated by multiplying the number of shares shown in the table by $2.98, the fair market value of our Class A Common Stock as of December 31, 2022, as determined by our board of directors.

(3) Dr. Lin acquired 2,800,000 shares of our Class A common stock pursuant to the Lin SPA. The shares subject to the Lin SPA vest as to 1/48 of the total on a monthly basis until all shares subject to the Lin SPA are vested on July 31, 2024, subject to Dr. Lin's continuous service with us as of each such date. If Dr. Lin is terminated by the company without cause or resigns for good reason (each as defined in the Lin SPA) within 12 months after a Sale Event (as defined in the 2020 Plan), the service-based requirement will be deemed satisfied in full.

(4) This amount reflects the number of shares underlying a grant of RSUs, representing a contingent right to receive 542,598 shares of our Class A Common Stock. The RSUs include both a performance-based vesting requirement and service-based vesting requirement. The performance-based requirement will be met upon the occurrence of a Liquidity Event. The service-based requirement was satisfied with respect to 25% of the shares on January 1, 2023 and the balance of the service-based requirement will be satisfied thereafter in 12 equal quarterly installments, subject to Dr. Lin's continued service with us as of each such date. As of December 31, 2022, none of the RSUs had vested as neither the performance-based requirement nor the service-based requirements had been satisfied. The performance-based requirement will be satisfied upon completion of this offering. If Dr. Lin is terminated by the company without cause or resigns for good reason (each as defined in the Lin SPA) within 12 months after a Sale Event (as defined in the 2020 Plan), the service-based requirement will be deemed satisfied in full.

(5) This amount reflects the number of shares underlying a grant of RSUs, representing a contingent right to receive 820,414 shares of our Class A Common Stock. 25% of the RSUs shall vest on November 17, 2023 and thereafter in 12 equal quarterly installments, subject to Dr. Lin's continued service with us as of each such date and the occurrence of a Liquidity Event. As of December 31, 2022, none of the RSUs had vested as neither the performance-based requirement nor the service-based requirements had been satisfied. The performance-based requirement will be satisfied upon completion of this offering. If Dr. Lin is terminated by the company without cause or resigns for good reason (each as defined in the Lin SPA) within 12 months after a Sale Event (as defined in the 2020 Plan), the service-based requirement will be deemed satisfied in full.

(6) This amount reflects the number of shares underlying a grant of RSUs, representing a contingent right to receive 820,414 shares of our Class A Common Stock. 100% of the RSUs shall vest on the occurrence of a Liquidity Event. Any unvested RSUs expire on the seven year anniversary of the grant date. As of December 31, 2022, none of the RSUs had vested as the performance-based requirement had not been satisfied. The performance-based requirement will be satisfied upon completion of this offering.

(7) Stock option award vests over a period of four years with 25% of the shares underlying the option vesting on the one year anniversary of the November 15, 2022 vesting commencement date and 1/48th of the shares underlying the option vesting on a monthly basis thereafter, subject to continued service through each vesting date.

(8) Stock option award vests over a period of four years with 25% of the shares underlying the option vesting on the one year anniversary of the November 8, 2022 vesting commencement date and 1/48th of the shares underlying the option vesting on a monthly basis thereafter, subject to continued service through each vesting date.

(9) Stock option award vests over a period of four years with 25% of the shares underlying the option vesting on the one year anniversary of the November 17, 2022 vesting commencement date and 1/48th of the shares underlying the option vesting on a monthly basis thereafter, subject to continued service through each vesting date.

We did not materially modify any outstanding equity awards held by our named executive officers in 2022.

Awards held by certain of our named executive officers may be eligible for accelerated vesting under specified circumstances, as described in more detail below under the subsection titled "—Potential Payments and Benefits Upon Termination or Change in Control."

We may in the future, on an annual basis or otherwise, grant additional equity awards to our executive officers pursuant to our 2023 Plan, the terms of which are described below under the subsection titled "—Equity Benefit Plans—2023 Equity Incentive Plan."

Emerging Growth Company Status

We are an "emerging growth company," as defined in the JOBS Act. As an emerging growth company we will be exempt from certain requirements related to executive compensation, including the requirements to hold a nonbinding advisory vote on executive compensation and to provide information relating to the ratio of total compensation of our chief executive officer to the median of the annual total compensation of all of our employees, each as required by the Investor Protection and Securities Reform Act of 2010, which is part of the Dodd-Frank Wall Street Reform and Consumer Protection Act.

Pension Benefits

Our named executive officers did not participate in, or otherwise receive any benefits under, any pension or retirement plan sponsored by us during the year ended December 31, 2022.

Nonqualified Deferred Compensation

Our named executive officers did not participate in, or earn any benefits under, a non-qualified deferred compensation plan sponsored by us during the year ended December 31, 2022.

Employment Agreements

We intend to enter into new executive employment agreements with our named executive officers prior to the completion of this offering.

Potential Payments and Benefits upon Termination or Change in Control

Regardless of the manner in which a named executive officer's service terminates, each named executive officer is entitled to receive amounts earned during her term of service, including unpaid salary.

Our named executive officers' stock awards granted prior to the execution of the underwriting agreement for this offering are subject to the terms of the 2020 Plan; a description of the termination and change in control provisions in the 2020 Plan and share options granted thereunder is provided in the subsection titled "—Equity Benefit Plans—2020 Stock Option and Grant Plan" below.

We intend to adopt a severance program covering our named executive officers in connection with this offering and will provide a description of such program once it is finalized.

Other Compensation and Benefits

All of our current named executive officers are eligible to participate in our employee benefit plans, which are provided through TriNet, in each case on the same basis as all of our other employees. These employee benefit plans include medical, dental, vision, short and long term disability and life and accidental

dismemberment insurance plans. We pay the premiums for the medical, dental, vision and life and accidental death and dismemberment insurance for all of our employees, including our named executive officers. We generally do not provide perquisites or personal benefits to our named executive officers. In addition, we provide the opportunity to participate in a 401(k) plan to our employees, including each of our named executive officers, as discussed in the subsection titled "—401(k) Plan" below.

401(k) Plan

Our named executive officers are eligible to participate in our defined contribution retirement plan that provides eligible employees with an opportunity to save for retirement on a tax advantaged basis. Eligible employees may elect to defer up to % of their eligible compensation into the plan on a pretax or after tax basis, up to annual limits prescribed by the Internal Revenue Code of 1986, as amended (the Code), with an annual match of up to 3% of the amount deferred, subject to the limitations of the Code.

Equity Benefit Plans

We believe that our ability to grant equity-based awards is a valuable and necessary compensation tool that aligns the long-term financial interests of our employees, consultants and directors with the financial interests of our stockholders. In addition, we believe that our ability to grant options and other equity-based awards helps us to attract, retain and motivate employees, consultants and directors, and encourages them to devote their best efforts to our business and financial success. The principal features of our equity incentive plans are summarized below. These summaries are qualified in their entirety by reference to the actual text of the plans, which are filed as exhibits to the registration statement of which this prospectus forms a part.

2023 Equity Incentive Plan

In , 2023, our board of directors adopted, and our stockholders approved, our 2023 Plan. We expect our 2023 Plan will become effective immediately prior to the execution of the underwriting agreement for this offering. Our 2023 Plan came into existence upon its adoption by our board of directors, but no grants will be made under our 2023 Plan prior to its effectiveness. Our 2023 Plan is a successor to and continuation of our 2020 Plan (referred to in the 2023 Plan as our Prior Plan). Once our 2023 Plan becomes effective, no further grants will be made under our 2020 Plan.

Types of Awards. Our 2023 Plan provides for the grant of incentive stock options (ISOs) to employees, including employees of any parent or subsidiary, and for the grant of nonstatutory stock options (NSOs), stock appreciation rights, restricted stock awards, restricted stock unit awards, performance awards and other forms of stock awards to employees, directors, and consultants, including employees and consultants of our affiliates.

Authorized Shares. Initially, the maximum number of shares of our Class A Common Stock that may be issued under our 2023 Plan after it becomes effective will not exceed shares, which is the sum of (i) new shares, plus (ii) an additional number of shares not to exceed , consisting of (a) shares that remain available for the issuance of awards under our 2020 Plan as of immediately prior to the effectiveness of our 2023 Plan and (b) shares of our Class A Common Stock that are subject to outstanding stock options or other stock awards granted under our 2020 Plan that, on or after the 2023 Plan becomes effective, terminate or expire prior to exercise or settlement; are not issued because the award is settled in cash; are forfeited because of the failure to vest; or are reacquired or withheld (or not issued) to satisfy a tax withholding obligation or the purchase or exercise price, if any, as such shares become available from time to time. In addition, the number of shares of our Class A Common Stock reserved for issuance under our 2023 Plan will automatically increase on January 1 of each calendar year, starting on January 1, 2024 (assuming the 2023 Plan becomes effective in 2023) through January 1, 2033, in an amount equal to % of the total number of shares of our capital stock outstanding on the last day of the calendar month before the date of each automatic increase, or a lesser number of shares determined by our board of directors. The maximum number of shares of our Class A Common Stock that may be issued on the exercise of ISOs under our 2023 Plan is .

Shares subject to stock awards granted under our 2023 Plan that expire or terminate without being exercised in full, or that are paid out in cash rather than in shares, do not reduce the number of shares available for issuance under our 2023 Plan. Additionally, shares become available for future grant under our 2023 Plan if they were issued stock awards under our 2023 Plan and we repurchase them or they are forfeited. This includes shares used to pay the exercise price of a stock award or to satisfy the tax withholding obligations related to a stock award.

Plan Administration. Our board of directors, or a duly authorized committee of our board of directors, will administer our 2023 Plan. Our board of directors may also delegate to one or more persons or bodies the authority to do one or more of the following: (i) designate recipients (other than officers) of specified stock awards, provided that no person or body may be delegated authority to grant a stock award to themself; (ii) determine the number of shares subject to such stock award; and (iii) determine the terms of such stock awards. Under our 2023 Plan, our board of directors has the authority to determine and amend the terms of awards and underlying agreements, including:

- recipients;
- the exercise, purchase or strike price of stock awards, if any;
- the number of shares subject to each stock award;
- the vesting schedule applicable to the awards, together with any vesting acceleration; and
- the form of consideration, if any, payable on exercise or settlement of the award.

Under the 2023 Plan, the board of directors also generally has the authority to effect, with the consent of any adversely affected participant:

- the reduction of the exercise, purchase, or strike price of any outstanding award;
- the cancellation of any outstanding award and the grant in substitution therefore of other awards, cash, or other consideration; or
- any other action that is treated as a repricing under generally accepted accounting principles.

Stock Options. ISOs and NSOs are granted under stock option agreements adopted by the plan administrator. The plan administrator determines the exercise price for stock options, within the terms and conditions of the 2023 Plan, provided that the exercise price of a stock option generally cannot be less than 100% of the fair market value of our Class A Common Stock on the date of grant. Options granted under the 2023 Plan vest at the rate specified in the stock option agreement as determined by the plan administrator.

Tax Limitations on ISOs. The aggregate fair market value, determined at the time of grant, of our Class A Common Stock with respect to ISOs that are exercisable for the first time by an optionholder during any calendar year under all of our stock plans may not exceed $100,000. Options or portions thereof that exceed such limit will generally be treated as NSOs. No ISO may be granted to any person who, at the time of the grant, owns or is deemed to own stock possessing more than 10% of our total combined voting power or that of any of our affiliates unless (i) the option exercise price is at least 110% of the fair market value of the stock subject to the option on the date of grant; and (ii) the option is not exercisable after the expiration of five years from the date of grant.

Restricted Stock Unit Awards. Restricted stock units are granted under restricted stock unit award agreements adopted by the plan administrator. Restricted stock units may be granted in consideration for any form of legal consideration that may be acceptable to our board of directors and permissible under applicable law. A restricted stock unit may be settled by cash, delivery of stock, a combination of cash and stock as deemed appropriate by the plan administrator, or in any other form of consideration set forth in the restricted stock unit agreement. Additionally, dividend equivalents may be credited in respect of shares covered by a restricted stock unit. Except as otherwise provided in the applicable award agreement, restricted stock units that have not vested will be forfeited once the participant’s continuous service ends for any reason.

Restricted Stock Awards. Restricted stock awards are granted under restricted stock award agreements adopted by the plan administrator. A restricted stock award may be awarded in consideration for cash, check, bank draft or money order, past services to us, or any other form of legal consideration that may be acceptable to our board of directors and permissible under applicable law. The plan administrator determines the terms and conditions of restricted stock awards, including vesting and forfeiture terms. If a participant's service relationship with us ends for any reason, we may receive any or all of the shares of our Class A Common Stock held by the participant that have not vested as of the date the participant terminates service with us through a forfeiture condition or a repurchase right.

Stock Appreciation Rights. Stock appreciation rights are granted under stock appreciation grant agreements adopted by the plan administrator. The plan administrator determines the purchase price or strike price for a stock appreciation right, which generally cannot be less than 100% of the fair market value of our Class A Common Stock on the date of grant. A stock appreciation right granted under the 2023 Plan vests at the rate specified in the stock appreciation right agreement as determined by the plan administrator.

Performance Awards. The 2023 Plan permits the grant of performance-based stock and cash awards. The plan administrator may structure awards so that the shares of our stock, cash, or other property will be issued or paid only following the achievement of certain pre-established performance goals during a designated performance period. The performance criteria that will be used to establish such performance goals may be based on any one of, or combination of, the following as determined by the plan administrator: earnings (including earnings per share and net earnings); earnings before interest, taxes and depreciation; earnings before interest, taxes, depreciation and amortization; total stockholder return; return on equity or average stockholder's equity; return on assets, investment, or capital employed; share price; margin (including gross margin); income (before or after taxes); operating income; operating income after taxes; pre-tax profit; operating cash flow; sales or revenue targets; increases in revenue or product revenue; expenses and cost reduction goals; improvement in or attainment of working capital levels; economic value added (or an equivalent metric); market share; cash flow; cash flow per share; share price performance; debt reduction; customer satisfaction; stockholder's equity; capital expenditures; debt levels; operating profit or net operating profit; workforce diversity; growth of net income or operating income; billings; preclinical development related compound goals; financing; regulatory milestones, including approval of a compound; stockholder liquidity; corporate governance and compliance; product commercialization; intellectual property; personnel matters; progress of internal research or clinical programs; progress of partnered programs; partner satisfaction; budget management; clinical achievements; completing phases of a clinical trial (including the treatment phase); announcing or presenting preliminary or final data from clinical trials, in each case, whether on particular timelines or generally; timely completion of clinical trials; submission of INDs and BLAs and other regulatory achievements; partner or collaborator achievements; internal controls, including those related to the Sarbanes-Oxley Act of 2002; research progress, including the development of programs; investor relations, analysts and communication; manufacturing achievements (including obtaining particular yields from manufacturing runs and other measurable objectives related to process development activities); strategic partnerships or transactions (including in-licensing and out-licensing of intellectual property); establishing relationships with commercial entities with respect to the marketing, distribution and sale of the Company's product candidates (including with group purchasing organizations, distributors and other vendors); supply chain achievements (including establishing relationships with manufacturers or suppliers of active pharmaceutical ingredients and other component materials and manufacturers of the Company's product candidates); co-development, co-marketing, profit sharing, joint venture or other similar arrangements; individual performance goals; corporate development and planning goals; and other measures of performance selected by the plan administrator.

The performance goals may be based on a company-wide basis, with respect to one or more business units, divisions, affiliates, or business segments, and in either absolute terms or relative to the performance of one or more comparable companies or the performance of one or more relevant indices. Unless specified otherwise (i) in the award agreement at the time the award is granted or (ii) in such other document setting forth the performance goals at the time the goals are established, we will appropriately make adjustments in the method of

calculating the attainment of performance goals as follows: (1) to exclude restructuring and/or other nonrecurring charges; (2) to exclude exchange rate effects; (3) to exclude the effects of changes to generally accepted accounting principles; (4) to exclude the effects of any statutory adjustments to corporate tax rates; (5) to exclude the effects of items that are "unusual" in nature or occur "infrequently" as determined under generally accepted accounting principles; (6) to exclude the dilutive effects of acquisitions or joint ventures; (7) to assume that any business divested by us achieved performance objectives at targeted levels during the balance of a performance period following such divestiture; (8) to exclude the effect of any change in the outstanding shares of our Class A Common Stock by reason of any stock dividend or split, stock repurchase, reorganization, recapitalization, merger, consolidation, spin-off, combination or exchange of shares or other similar corporate change, or any distributions to common stockholders other than regular cash dividends; (9) to exclude the effects of stock based compensation and the award of bonuses under our bonus plans; (10) to exclude costs incurred in connection with potential acquisitions or divestitures that are required to be expensed under generally accepted accounting principles; (11) to exclude the goodwill and intangible asset impairment charges that are required to be recorded under generally accepted accounting principles; and (12) to exclude the effects of the timing of acceptance for review and/or approval of submissions to the FDA, EMA or other comparable regulatory authority. In addition, we retain the discretion to reduce or eliminate the compensation or economic benefit due upon attainment of the goals. The performance goals may differ from participant to participant and from award to award.

Other Stock Awards. The plan administrator may grant other awards based in whole or in part by reference to our Class A Common Stock. The plan administrator will set the number of shares under the stock award and all other terms and conditions of such awards.

Non-Employee Director Compensation Limit. The aggregate value of all compensation granted or paid to any non-employee director with respect to any calendar year, including stock awards granted and cash fees paid by us to such non-employee director, will not exceed $ in total value, or in the event such non-employee director is first appointed or elected to the board during such calendar year, $ in total value (in each case, calculating the value of any such stock awards based on the grant date fair value of such stock awards for financial reporting purposes).

Changes to Capital Structure. In the event there is a specified type of change in our capital structure, such as a stock split, reverse stock split, or recapitalization, appropriate adjustments will be made to (i) the class and maximum number of shares reserved for issuance under the 2023 Plan, (ii) the class and maximum number of shares by which the share reserve may increase automatically each year, (iii) the class and maximum number of shares that may be issued on the exercise of ISOs, and (iv) the class and number of shares and exercise price, strike price, or purchase price, if applicable, of all outstanding stock awards.

Corporate Transactions. The following applies to stock awards under the 2023 Plan in the event of a corporate transaction, unless otherwise provided in a participant's stock award agreement or other written agreement with us or one of our affiliates or unless otherwise expressly provided by the plan administrator at the time of grant.

In the event of a corporate transaction, any stock awards outstanding under the 2023 Plan may be assumed, continued or substituted for by any surviving or acquiring corporation (or its parent company), and any reacquisition or repurchase rights held by us with respect to the stock award may be assigned to the successor (or its parent company). If the surviving or acquiring corporation (or its parent company) does not assume, continue or substitute for such stock awards, then with respect to any such stock awards that are held by participants whose continuous service has not terminated prior to the effective time of the transaction, or current participants, the vesting (and exercisability, if applicable) of such stock awards will be accelerated in full to a date prior to the effective time of the transaction (contingent upon the effectiveness of the transaction), and such stock awards will terminate if not exercised (if applicable) at or prior to the effective time of the transaction, and any reacquisition or repurchase rights held by us with respect to such stock awards will lapse (contingent upon the effectiveness of the transaction). With respect to performance awards with multiple vesting levels depending on

performance level, unless otherwise provided by an award agreement or by the administrator, the award will accelerate at 100% of target. If the surviving or acquiring corporation (or its parent company) does not assume, continue or substitute for such stock awards, then with respect to any such stock awards that are held by persons other than current participants, such awards will terminate if not exercised (if applicable) prior to the effective time of the transaction, except that any reacquisition or repurchase rights held by us with respect to such stock awards will not terminate and may continue to be exercised notwithstanding the transaction. The plan administrator is not obligated to treat all stock awards or portions of stock awards in the same manner and is not obligated to take the same actions with respect to all participants.

In the event a stock award will terminate if not exercised prior to the effective time of a transaction, the plan administrator may provide, in its sole discretion, that the holder of such stock award may not exercise such stock award but instead will receive a payment equal in value to the excess (if any) of (i) the value of the property the participant would have received upon the exercise of the stock award over (ii) any exercise price payable by such holder in connection with such exercise.

Under our 2023 Plan, a corporate transaction is defined to include: (i) a sale of all or substantially all of our assets; (ii) the sale or disposition of more than 50% of our outstanding securities; (iii) the consummation of a merger or consolidation where we do not survive the transaction; and (iv) the consummation of a merger or consolidation where we do survive the transaction but the shares of our Class A Common Stock outstanding before such transaction are converted or exchanged into other property by virtue of the transaction, unless otherwise provided in an award agreement or other written agreement between us and the award holder.

Change in Control. In the event of a change in control, as defined under our 2023 Plan, awards granted under our 2023 Plan will not receive automatic acceleration of vesting and exercisability, although this treatment may be provided for in an award agreement.

Under the 2023 Plan, a change in control is defined to include: (i) the acquisition by any person or company of more than 50% of the combined voting power of our then outstanding stock; (ii) a consummated merger, consolidation or similar transaction in which our stockholders immediately before the transaction do not own, directly or indirectly, more than 50% of the combined voting power of the surviving entity (or the parent of the surviving entity); (iii) the approval by the stockholders or the board of directors of a plan of our complete dissolution or liquidation, or the occurrence of our complete dissolution or liquidation , except for a liquidation into a parent corporation; (iv) a consummated sale, lease, exclusive license or other disposition of all or substantially all of our assets other than to an entity more than 50% of the combined voting power of which is owned by our stockholders; and (v) an unapproved change in the majority of the board of directors.

Transferability. A participant may not transfer stock awards under our 2023 Plan other than by will, the laws of descent and distribution, or as otherwise provided under our 2023 Plan.

Plan Amendment or Termination. Our board of directors has the authority to amend, suspend, or terminate our 2023 Plan, provided that such action does not materially impair the existing rights of any participant without such participant's written consent. Certain material amendments also require the approval of our stockholders. No ISOs may be granted after the tenth anniversary of the date our board of directors adopted our 2023 Plan. No stock awards may be granted under our 2023 Plan while it is suspended or after it is terminated.

2020 Stock Option and Grant Plan

Our board of directors adopted, and our stockholders approved, the 2020 Plan in October 2020. The 2020 Plan was most recently amended in January 2023. The 2020 Plan will be terminated on the date the 2023 Plan becomes effective, and thereafter no further stock awards will be granted under the 2020 Plan. However, any outstanding stock awards granted under the 2020 Plan will remain outstanding, subject to the terms of our 2020 Plan and award agreements, until such outstanding options are exercised or until any stock awards terminate or expire by their terms.

Types of Awards. The 2020 Plan allows for the grant of ISOs to our employees and to any of our subsidiary corporations' employees, and for the grant of nonqualified stock options, restricted stock, unrestricted stock, and restricted stock units awards to our employees, officers, directors and consultants and those of our subsidiary corporations.

Authorized Shares. Subject to certain capitalization adjustments, the aggregate number of shares of our Class A Common Stock that may be issued pursuant to stock awards under the 2020 Plan will not exceed 17,436,925 shares. The maximum number of shares of our Class A Common Stock that may be issued pursuant to the exercise of ISOs under our 2020 Plan is 174,369,250 shares. The shares we have issued under the 2020 Plan have been authorized but unissued shares or shares we reacquired. The shares of Class A Common Stock underlying any awards that are (i) forfeited, (ii) canceled, (iii) reacquired by the Company prior to vesting, (iv) satisfied without the issuance of stock or otherwise terminated (other than by exercise), and (v) that are withheld upon exercise of an option or settlement of an award to cover the exercise price or tax withholding, will again become available for issuance under the 2020 Plan. Following this offering, such shares will be added to the shares of Class A Common Stock available for issuance under the 2023 Plan.

Plan Administration. The 2020 Plan is administered by our board of directors or a committee appointed by it (the plan administrator). The plan administrator has full power to, among other things, select, from among the individuals eligible for awards, the individuals to whom awards will be granted, to accelerate the time at which a stock award may be exercised or vest, to amend the 2020 Plan and to determine the specific terms and conditions of each award, subject to the provisions of the 2020 Plan. The plan administrator may exercise its discretion to reduce the exercise price of outstanding stock options under the 2020 Plan or effect repricing through cancellation of such outstanding and by granting such holders new awards in replacement of the cancelled options in accordance with the terms of the 2020 Plan.

Stock Options. The exercise price per share of all stock options must equal at least 100% of the fair market value per share of our Class A Common Stock on the date of grant. The term of a stock option may not exceed ten years. An ISO granted to a participant who owns more than 10% of the total combined voting power of all classes of our stock on the date of grant, or any subsidiary corporations, may not have a term in excess of five years and must have an exercise price of at least 110% of the fair market value per share of our Class A Common Stock on the date of grant. The plan administrator will determine the methods of payment of the exercise price of an option, which may include cash, shares or certain other property or other consideration acceptable to the plan administrator. After a participant's termination of service, the participant generally may exercise his or her stock options, to the extent vested as of such date of termination, during a period of 90 days after termination of service. If a termination of service is due to death or disability, the option generally will remain exercisable, to the extent vested as of such date of termination, until the one-year anniversary of such termination of service. However, in no event may an option be exercised later than the expiration of its term. If a termination of service is for cause (as defined in an applicable award agreement), the stock option automatically expires upon the date of the termination of service.

Restricted Stock. Restricted stock awards are grants of shares of our Class A Common Stock that are subject to various restrictions, including restrictions on transferability and forfeitures provisions. Shares of restricted stock will vest, and the restrictions on such shares will lapse, in accordance with terms and conditions established by the plan administrator.

Unrestricted Stock. Unrestricted stock awards may be granted to participants in recognition of past services or for other valid consideration and may be issued in lieu of cash compensation due to such participant.

Restricted Stock Units. A restricted stock unit is an award that covers a number of shares of our Class A Common Stock that may be settled upon vesting in cash, by the issuance of the underlying shares or a combination of both. The plan administrator determines the terms and conditions of restricted stock units, including the number of units granted, the vesting criteria (which may include specified performance criteria and/or continued service to us) and the form and timing of payment.

Changes to Capital Structure. In the event of certain changes in our capitalization, the exercise prices of and the number of shares subject to outstanding awards, and the purchase price of and the numbers of shares subject to outstanding awards will be proportionately adjusted, subject to any required action by our board of directors or stockholders.

Sale Events. The 2020 Plan provides that upon the effectiveness of a "sale event," as defined in the 2020 Plan, an acquirer or successor entity may assume, continue or substitute for the outstanding awards under the 2020 Plan. To the extent that awards granted under the 2020 Plan are not assumed or continued or substituted by acquirer or the successor entity, all stock options and all other awards granted under the 2020 Plan shall terminate. In the event of such termination, individuals holding stock options will be permitted to exercise such options (to the extent exercisable) prior to the consummation of the sale event. In addition, in connection with the termination of the 2020 Plan upon a sale event, we may make or provide for a cash payment equal to (i) in the case of vested and exercisable options, the difference between (1) the per share cash consideration payable to stockholders (as determined by the plan administrator) in the sale event times the number of shares subject to the options being cancelled and (2) the aggregate exercise price of the options and (ii) in the case of restricted stock and restricted stock unit awards, the per share cash consideration payable to stockholders in the sale event multiplied by the number of shares of stock subject to such stock awards (payable at the time of the sale event or upon the later vesting of the awards). In the event of the forfeiture of shares of restricted stock issued under the 2020 Plan, such shares of restricted stock shall be repurchased from the holder at a price per share equal to the original per share purchase price paid by the recipient of such shares. Additionally, our board of directors may resolve, in its sole discretion, to subject any assumed options or payments in respect of options to any escrow, holdback, indemnification, earn-out or similar provisions in the transaction agreements as such provisions apply to holders of our Class A Common Stock.

Transferability. The 2020 Plan generally does not allow for the transfer or assignment of awards, other than, at the discretion of the plan administrator, by gift to an immediate family member, to trusts for the benefit of family members, or to partnerships in which such family members are the only partners, and only the recipient of an award may exercise such an award during his or her lifetime.

Plan Amendment or Termination. Our board of directors may amend, suspend, or terminate the 2020 Plan at any time and for any reason, provided that stockholder approval is obtained where such approval is required by applicable law.

2023 Employee Stock Purchase Plan

Our board of directors adopted, and our stockholders approved, our 2023 Employee Stock Purchase Plan, (ESPP) in 2023. The ESPP will become effective immediately prior to the execution of the underwriting agreement for this offering. The purpose of the ESPP is to secure and retain the services of new employees, to retain the services of existing employees, and to provide incentives for such individuals to exert maximum efforts toward our success and that of our affiliates. Our ESPP will include two components. One component will be designed to allow eligible U.S. employees to purchase our ordinary shares in a manner that may qualify for favorable tax treatment under Section 423 of the Code. The other component will permit the grant of purchase rights that do not qualify for such favorable tax treatment in order to allow deviations necessary to permit participation by eligible employees who are foreign nationals or employed outside of the U.S. while complying with applicable foreign laws.

Share Reserve. Following this offering, the ESPP authorizes the issuance of shares of our Class A Common Stock under purchase rights granted to our employees or to employees of any of our designated affiliates. The number of shares of our Class A Common Stock reserved for issuance will automatically increase on January 1 of each calendar year, beginning on January 1, 2024 (assuming the ESPP becomes effective in 2023) through January 1, 2033, by the lesser of (i) % of the total number of shares of our capital stock outstanding on the last day of the calendar month before the date of the automatic increase, and (ii) shares; provided

that before the date of any such increase, our board of directors may determine that such increase will be less than the amount set forth in clauses (i) and (ii). As of the date hereof, no shares of our Class A Common Stock have been purchased under the ESPP.

Administration. Our board of directors, or a duly authorized committee thereof, will administer our ESPP. Our board may delegate concurrent authority to administer the ESPP to our compensation committee under the terms of the compensation committee's charter. The ESPP is implemented through a series of offerings under which eligible employees are granted purchase rights to purchase shares of our Class A Common Stock on specified dates during such offerings. Under the ESPP, we may specify offerings with durations of not more than 27 months and may specify shorter purchase periods within each offering. Each offering will have one or more purchase dates on which shares of our Class A Common Stock will be purchased for employees participating in the offering. An offering under the ESPP may be terminated under certain circumstances.

Payroll Deductions. Generally, all regular employees, including executive officers, employed by us or by any of our designated affiliates, may participate in the ESPP and may contribute, normally through payroll deductions, up to % of their earnings (as defined in the ESPP) for the purchase of our Class A Common Stock under the ESPP. Unless otherwise determined by our board of directors, Class A Common Stock will be purchased for the accounts of employees participating in the ESPP at a price per share that is at least the lesser of (i) 85% of the fair market value of a share of our Class A Common Stock on the first date of an offering; or (ii) 85% of the fair market value of a share of our Class A Common Stock on the date of purchase.

Limitations. Employees may have to satisfy one or more of the following service requirements before participating in the ESPP, as determined by our board of directors, including: (i) customary employment with us or one of our affiliates for more than 20 hours per week and more than five months per calendar year; or (ii) continuous employment with us or one of our affiliates for a minimum period of time (not to exceed two years). No employee may purchase shares under the ESPP at a rate in excess of $25,000 worth of our Class A Common Stock based on the fair market value per share of our Class A Common Stock at the beginning of an offering for each year such a purchase right is outstanding. Finally, no employee will be eligible for the grant of any purchase rights under the ESPP if immediately after such rights are granted, such employee has voting power over 5% or more of our outstanding capital stock measured by vote or value under Section 424(d) of the Code.

Changes to Capital Structure. In the event that there occurs a change in our capital structure through such actions as a stock split, merger, consolidation, reorganization, recapitalization, reincorporation, stock dividend, dividend in property other than cash, large nonrecurring cash dividend, liquidating dividend, combination of shares, exchange of shares, change in corporate structure, or similar transaction, the board of directors will make appropriate adjustments to: (i) the number of shares reserved under the ESPP; (ii) the maximum number of shares by which the share reserve may increase automatically each year; (iii) the number of shares and purchase price of all outstanding purchase rights; and (iv) the number of shares that are subject to purchase limits under ongoing offerings.

Corporate Transactions. In the event of certain significant corporate transactions, including: (i) a sale of all or substantially all of our assets; (ii) the sale or disposition of more than 50% of our outstanding securities; (iii) the consummation of a merger or consolidation where we do not survive the transaction; and (iv) the consummation of a merger or consolidation where we do survive the transaction but the shares of our Class A Common Stock outstanding immediately before such transaction are converted or exchanged into other property by virtue of the transaction, any then-outstanding rights to purchase our stock under the ESPP may be assumed, continued or substituted for by any surviving or acquiring entity (or its parent company). If the surviving or acquiring entity (or its parent company) elects not to assume, continue, or substitute for such purchase rights, then the participants' accumulated payroll contributions will be used to purchase shares of our Class A Common Stock within ten business days before such corporate transaction, and such purchase rights will terminate immediately.

ESPP Amendment or Termination. Our board of directors has the authority to amend or terminate our ESPP, provided that except in certain circumstances such amendment or termination may not materially impair any outstanding purchase rights without the holder's consent. We will obtain stockholder approval of any amendment to our ESPP as required by applicable law or listing requirements.

Limitations on Liability and Indemnification

Our amended and restated certificate of incorporation, which will become effective immediately prior to the closing of this offering, will contain provisions that limit the liability of our current and former directors and officers for monetary damages to the fullest extent permitted by Delaware law. Delaware law provides that directors and officers of a corporation will not be personally liable for monetary damages for any breach of fiduciary duties as directors or officers, except liability for:

- any breach of the director's or officer's duty of loyalty to the corporation or its stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- as a director, unlawful payments of dividends or unlawful stock repurchases or redemptions;
- as an officer, derivative claims brought on behalf of the corporation by a stockholder; or
- any transaction from which the director or officer derived an improper personal benefit.

Such limitation of liability does not apply to liabilities arising under federal securities laws and does not affect the availability of equitable remedies such as injunctive relief or rescission.

Our amended and restated certificate of incorporation will authorize us to indemnify our directors, officers, employees and other agents to the fullest extent permitted by Delaware law. Our amended and restated bylaws will provide that we are required to indemnify our directors and officers to the fullest extent permitted by Delaware law and may indemnify our other employees and agents. Our amended and restated bylaws will also provide that, on satisfaction of certain conditions, we will advance expenses incurred by a director or officer in advance of the final disposition of any action or proceeding, and permit us to secure insurance on behalf of any officer, director, employee, or other agent for any liability arising out of his or her actions in that capacity regardless of whether we would otherwise be permitted to indemnify him or her under the provisions of Delaware law. We have entered and expect to continue to enter into agreements to indemnify our directors, executive officers and other employees as determined by the board of directors. With certain exceptions, these agreements provide for indemnification for related expenses including attorneys' fees, judgments, fines and settlement amounts incurred by any of these individuals in any action or proceeding.

We believe that these amended and restated certificate of incorporation and amended and restated bylaw provisions and indemnification agreements are necessary to attract and retain qualified persons as directors and officers. We also maintain customary directors' and officers' liability insurance.

The limitation of liability and indemnification provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage stockholders from bringing a lawsuit against our directors for breach of their fiduciary duty. They may also reduce the likelihood of derivative litigation against our directors and officers, even though an action, if successful, might benefit us and other stockholders. Further, a stockholder's investment may be adversely affected to the extent that we pay the costs of settlement and damage awards against directors and officers as required by these indemnification provisions.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted for directors, executive officers, or persons controlling us, we have been informed that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

Rule 10b5-1 Plans

Our directors, officers and key employees may adopt written plans, known as Rule 10b5-1 plans, in which they will contract with a broker to buy or sell shares of our Class A Common Stock on a periodic basis. Under a Rule 10b5-1 plan, a broker executes trades under parameters established by the director or officer when entering into the plan, without further direction from them. The director or officer may amend a Rule 10b5-1 plan in some circumstances and may terminate a plan at any time. Our directors and executive officers may also buy or sell additional shares outside of a Rule 10b5-1 plan when they do not possess of material nonpublic information, subject to compliance with the terms of our insider trading policy.

CERTAIN RELATIONSHIPS AND RELATED PERSON TRANSACTIONS

The following includes a summary of transactions since our inception and any currently proposed transactions to which we have been or are to be a party in which the amount involved exceeded or will exceed $120,000, and in which any of our directors, executive officers or, to our knowledge, beneficial owners of more than 5% of our capital stock or any member of the immediate family of any of the foregoing persons had or will have a direct or indirect material interest, other than equity and other compensation, arrangements which are described under the sections titled "Executive Compensation" and "Management—Non-Employee Director Compensation."

Series A Preferred Stock Financing

In a closing held on October 9, 2020, we issued and sold an aggregate of 8,000,000 shares of our Series A redeemable convertible preferred stock at a purchase price of $1.00 per share for an aggregate purchase price of $8,000,000.

The following table summarizes the Series A redeemable convertible preferred stock purchased by holders of more than 5% of our capital stock as of the date of the closing of the Series A Preferred Stock financing, entities affiliated with our executive officers, and members of our board of directors.

Participants[1]	Shares of Series A Preferred Stock Purchased (#)	Aggregate Purchase Price ($)
Westlake BioPartners Fund II, L.P.[2]	8,000,000	8,000,000

(1) Additional details regarding these stockholders and their equity holdings are included in the section titled "Principal Stockholders."
(2) Dr. Seidenberg is a member of our board of directors, Dr. Harper is a former member of our board of directors and both are founding managing directors of Westlake BioPartners Fund II, L.P. (together with its affiliates, Westlake). Dr. Seidenberg and Dr. Harper may be deemed to share the power to direct the disposition and vote of the shares held by Westlake, but disclaims beneficial ownership of all shares held by Westlake except to any pecuniary interest therein.

Series B Preferred Stock Financing

In multiple closings held between October 19, 2021 and February 4, 2022, we issued and sold an aggregate of 48,230,900 shares of our Series B redeemable convertible preferred stock at a purchase price of $5.1834 per share for an aggregate purchase price of $250,000,047.

The following table summarizes the Series B redeemable convertible preferred stock purchased by holders of more than 5% of our capital stock as of the date of the second closing of the Series B Preferred Stock financing, entities affiliated with our executive officers, and members of our board of directors.

Participants[1]	Shares of Series B Preferred Stock Purchased (#)	Aggregate Purchase Price ($)
Westlake BioPartners Fund II, L.P.[2]	4,823,090	25,000,005
Citadel Multi-Strategy Equities Master Fund Ltd.	5,787,708	30,000,006
AyurMaya Capital Management Fund, L.P.	11,093,106	57,500,006
venBio Global Strategic Fund IV, L.P.[3]	4,823,090	25,000,005
Entities affiliated with Orbimed[4]	4,823,090	25,000,000
Aquila Investments XIX	3,858,472	20,000,004
Woodland Hills Partners LLC[5]	1,929,236	10,000,002

(1) Additional details regarding these stockholders and their equity holdings are included in the section titled "Principal Stockholders."
(2) Dr. Seidenberg is a member of our board of directors, Dr. Harper is a former member of our board of directors and both are founding managing directors of Westlake BioPartners Fund II, L.P. (together with its affiliates, Westlake). Dr. Seidenberg and Dr. Harper may be deemed to share the power to direct the disposition and vote of the shares held by Westlake, but disclaims beneficial ownership of all shares held by Westlake except to any pecuniary interest therein.
(3) Dr. Gaster is a former member of our board of directors and a managing director of venBio Global Strategic Fund IV, L.P. Dr. Gaster may be deemed to share the power to direct the disposition and vote of the shares held by venBio Global Strategic Fund IV, L.P., but disclaims beneficial ownership of all shares held by venBio Global Strategic Fund IV, L.P. except to any pecuniary interest therein.
(4) Consists of (i) 4,533,706 shares of Series B redeemable convertible preferred stock issued to Orbimed Private Investments VIII, LP and (ii) 289,384 shares of Series B Preferred Stock issued to Orbimed Genesis Master Fund, L.P. (together with Orbimed Private Investments VIII, L.P. and other affiliates, Orbimed).
(5) Dr. Lin, Mr. Machado and Dr. Peloso are officers and/or members of our board of directors; Mr. Carey is one of our former executive officers and directors. Dr. Lin and Mr. Carey are managing members and Mr. Machado and Dr. Peloso are each members of Woodland Hills Partners LLC.

Series C Preferred Stock Financing

In a closing held on September 9, 2022, we issued and sold an aggregate of 24,115,368 shares of our Series C redeemable convertible preferred stock at a purchase price of $6.2201 per share for an aggregate purchase price of $150,000,001.

The following table summarizes the Series C redeemable convertible preferred stock purchased by holders of more than 5% of our capital stock as of the date of the closing of the Series C Preferred Stock financing, entities affiliated with our executive officers, and members of our board of directors.

Participants[1]	Shares of Series C Preferred Stock Purchased (#)	Aggregate Purchase Price ($)
AI ACEL LLC[2]	4,823,074	30,000,003
Westlake BioPartners Fund II, L.P.[3]	4,019,228	25,000,000
Citadel Multi-Strategy Equities Master Fund Ltd.	562,692	3,500,001
AyurMaya Capital Management Fund, LP	7,314,995	45,500,000
venBio Global Strategic Fund IV, L.P.[4]	1,205,768	7,499,998
Entities affiliated with Orbimed[5]	3,215,382	19,999,998
Woodland Hills Partners LLC[6]	361,731	2,250,003

(1) Additional details regarding these stockholders and their equity holdings are included in the section titled "Principal Stockholders."
(2) Dr. Becker, a member of our board of director, was designated to our board of directors by AI ACEL LLC.
(3) Dr. Seidenberg is a member of our board of directors, Dr. Harper is a former member of our board of directors and both are founding managing directors of Westlake BioPartners Fund II, L.P. (together with its affiliates, Westlake). Dr. Seidenberg and Dr. Harper may be deemed to share the power to direct the disposition and vote of the shares held by Westlake, but disclaims beneficial ownership of all shares held by Westlake except to any pecuniary interest therein.
(4) Dr. Gaster is a former member of our board of directors and a managing director of venBio Global Strategic Fund IV, L.P. Dr. Gaster may be deemed to share the power to direct the disposition and vote of the shares held by venBio Global Strategic Fund IV, L.P., but disclaims beneficial ownership of all shares held by venBio Global Strategic Fund IV, L.P. except to any pecuniary interest therein.
(5) Consists of (i) 2,974,228 shares of Series C redeemable convertible preferred stock issued to Orbimed Private Investments VIII, LP and (ii) 241,154 shares of Series C redeemable convertible preferred stock issued to Orbimed Genesis Master Fund, L.P.
(6) Dr. Lin, Mr. Machado and Dr. Peloso are officers and/or members of our board of directors; Mr. Carey is one of our former executive officers and directors. Dr. Lin and Mr. Carey are managing members and Mr. Machado and Dr. Peloso are each members of Woodland Hills Partners LLC.

Investors' Rights Agreement

On September 9, 2022, we entered into an Amended and Restated Investors' Rights Agreement (the Rights Agreement) with certain holders of more than 5% of our outstanding capital stock, including Westlake, Citadel Multi-Strategy Equities Master Fund Ltd. (together with its affiliates, Citadel), Orbimed and AyurMaya Capital Management Fund, LP (together with its affiliates, Matrix), as well as Woodland Hills Partners LLC, which is affiliated with certain of our directors and officers.

The Rights Agreement grants to the holders of our outstanding redeemable convertible preferred stock certain rights, including certain registration rights with respect to the registrable securities held by them. See the section titled "Description of Capital Stock—Registration Rights" for additional information. In addition, the Rights Agreement imposed certain affirmative obligations on us, including our obligation to, among other things, (i) grant each holder who holds at least 20% of our registrable securities (the Major Investors) a right of first offer with respect to future sales of our equity, excluding the shares to be offered and sold in this offering, and (ii) grant certain information and inspection rights to such Major Investors. Each of these obligations will terminate in connection with the closing of this offering.

Voting Agreement

On September 9, 2022, we entered into an Amended and Restated Voting Agreement (the Voting Agreement) with certain holders of more than 5% of our outstanding capital stock, including Westlake, Citadel, Orbimed, AI ACEL LLC and Matrix, as well as Woodland Hills Partners LLC, which is affiliated with certain of our directors and officers.

Pursuant to the Voting Agreement, as amended, (i) one director shall be designated by Westlake, (ii) one director shall be designated by Matrix, (iii) one director shall be designated by AI ACEL LLC, (iv) one director shall be our Chief Executive Officer, and (v) three directors who are industry representatives, are not otherwise our affiliate or employee or of any of our investors and are mutually acceptable to the other members of the board of directors shall be appointed (each such director, an independent director), one of whom shall initially be designated by venBio, until replaced by an independent director. See the section titled "Management—Composition of Our Board of Directors." The Voting Agreement will terminate by its terms in connection with the closing of this offering and none of our stockholders will have any continuing rights regarding the election or designation of members of our board of directors following this offering.

Right of First Refusal and Co-Sale Agreement

On September 9, 2022, we entered into an Amended and Restated Right of First Refusal and Co-Sale Agreement (the Co-Sale Agreement) with certain holders of more than 5% of our outstanding capital stock, including Westlake, Citadel, Orbimed, AI ACEL LLC and Matrix, as well as Woodland Hills Partners LLC, which is affiliated with certain of our directors and officers.

Pursuant to the Co-Sale Agreement, we had a right of first refusal in respect of certain sales of securities by certain holders of our Class A Common Stock and Class B Common Stock and redeemable convertible preferred stock. To the extent we do not exercise such right in full, certain holders of more than 5% of our outstanding capital stock, including Westlake, Citadel, Orbimed, AI ACEL LLC and Matrix, as well as Woodland Hills Partners LLC, which is affiliated with certain of our directors and officers, are granted certain rights of first refusal and co-sale in respect of such sale. The Co-Sale Agreement will terminate in connection with the closing of this offering.

Limitations on Liability and Indemnification Agreements

Our amended and restated certificate of incorporation will contain provisions limiting the liability of directors and officers, and our amended and restated bylaws will provide that we will indemnify each of our directors and executive officers to the fullest extent permitted under Delaware law. Our amended and restated certificate of incorporation and amended and restated bylaws will also provide our board of directors with discretion to indemnify our employees and other agents when determined appropriate by the board. In addition, we have entered into or intend to enter into an indemnification agreement with each of our directors and executive officers, which will require us to indemnify them. For more information regarding these agreements, see the section titled "Executive Compensation—Limitations on Liability and Indemnification."

Policies and Procedures for Transactions with Related Persons

We intend to adopt a written related-person transactions policy prior to the completion of this offering that sets forth our policies and procedures regarding the identification, review, consideration and oversight of "related-person transactions." For purposes of our policy only, a "related-person transaction" is a transaction, arrangement or relationship (or any series of similar transactions, arrangements or relationships) involving an amount that exceeds $120,000 in which we are participant and in which a "related person" has a material interest. Transactions involving compensation for services provided to us as an employee, consultant or director are not considered related-person transactions under this policy. A related person is any executive officer, director, nominee to become a director or a beneficial owner of more than 5% of our Class A Common Stock, including any of their immediate family members and affiliates, including entities owned or controlled by such persons.

Under the policy, where a transaction has been identified as a related-person transaction, management must present information regarding the proposed related-person transaction to our audit committee (or, where review by our audit committee would be inappropriate, to another independent body of our board of directors) for review. The presentation must include a description of, among other things, all of the parties thereto, the direct and indirect interests of the related persons, the purpose of the transaction, the material facts, the benefits of the

transaction to us and whether any alternative transactions are available, an assessment of whether the terms are comparable to the terms available from unrelated third parties and management's recommendation. To identify related-person transactions in advance, we rely on information supplied by our executive officers, directors and certain significant stockholders. In considering related-person transactions, our audit committee or another independent body of our board of directors takes into account the relevant available facts and circumstances including, but not limited to:

- the risks, costs and benefits to us;
- the impact on a director's independence in the event the related person is a director, immediate family member of a director or an entity with which a director is affiliated;
- the terms of the transaction;
- the availability of other sources for comparable services or products; and
- the terms available to or from, as the case may be, unrelated third parties.

PRINCIPAL STOCKHOLDERS

The following table sets forth information regarding beneficial ownership of our capital stock as of , 2023 by:

- each person, or group of affiliated persons, known by us to beneficially own more than 5% of our Class A Common Stock;
- each of our directors;
- each our of named executive officers; and
- all of our current executive officers and directors as a group.

We have determined beneficial ownership in accordance with the rules and regulations of the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Except as indicated by the footnotes below, we believe, based on information furnished to us, that the persons and entities named in the table below have sole voting and sole investment power with respect to all shares that they beneficially own, subject to applicable community property laws.

Applicable percentage ownership before the offering is based on shares of our Class A Common Stock outstanding as of , 2023, after giving effect to the automatic conversion of outstanding shares of our redeemable convertible preferred stock into an equivalent number of shares of our Class A Common Stock immediately prior to the closing of this offering, and no shares of Class B Common Stock outstanding.

Applicable percentage ownership after the offering is based on shares of our Class A Common Stock outstanding immediately after the closing of this offering (assuming no exercise of the underwriters' option to purchase additional shares), after giving effect to the automatic conversion of outstanding shares of our redeemable convertible preferred stock into an equivalent number of shares of our Class A Common Stock immediately prior to the closing of this offering, and no shares of Class B Common Stock outstanding. In computing the number of shares beneficially owned by a person and the percentage ownership of such person, we deemed to be outstanding all shares of Class A Common Stock issuable pursuant to the exercise of stock options that are exercisable and all RSUs that will vest within 60 days of , 2023 (for some of which the liquidity-based vesting condition will be satisfied upon completion of this offering). However, except as described above, we did not deem such shares outstanding for the purpose of computing the percentage ownership of any other person. The percentage ownership information does not reflect any potential purchases of any shares of Class A Common Stock in this offering by the beneficial owners identified in the table below.

Unless otherwise indicated, the address for each beneficial owner listed in the table below is c/o ACELYRIN, INC., 4149 Liberty Canyon Road, Agoura Hills, California 91301.

	Number of Shares Beneficially Owned (#)		Percentage of Shares Beneficially Owned (%)	
Name of Beneficial Owner	Before the Offering (#)	After the Offering (#)	Before the Offering (%)	After the Offering (%)
Greater than 5% Holders:				
Westlake Village BioPartners Fund II, L.P.(1)				
AyurMaya Capital Management Fund, L.P. (Matrix)(2)				
Citadel Multi-Strategy Equities Master Fund Ltd. (Surveyor)(3)				
Entities affiliated with Orbimed(4)				
Opaleye, L.P.(5)				
Directors and Named Executive Officers:				
Shao-Lee Lin, M.D., Ph.D.(6)				
Mardi C. Dier(7)				
Melanie Gloria(8)				
Dan Becker, M.D., Ph.D.(9)				
Alan Colowick, M.D., M.P.H.(10)				
Bruce C. Cozadd(11)				
Patrick Machado J.D.(12)				
Beth Seidenberg M.D.(13)				
Dawn Svoronos(14)				
All directors and executive officers as a group (12 persons)(15)				

* Represents beneficial ownership of less than 1%.

DESCRIPTION OF CAPITAL STOCK

General

The following description of our capital stock and certain provisions of our amended and restated certificate of incorporation and amended and restated bylaws are summaries and are qualified by reference to the amended and restated certificate of incorporation, which will become effective immediately prior to the closing of this offering, and the amended and restated bylaws, which will become effective upon the closing of this offering. Copies of these documents have been filed with the SEC as exhibits to our registration statement, of which this prospectus forms a part. The descriptions of the Class A Common Stock, Class B Common Stock and preferred stock reflect changes to our capital structure that will be in effect on the closing of this offering.

Upon filing of our amended and restated certificate of incorporation and the closing of this offering, our authorized capital stock will consist of shares of Class A Common Stock, par value $0.00001 per share, shares of Class B Common Stock, par value $0.00001 per share and shares of preferred stock, par value $0.00001 per share. All of our authorized shares of preferred stock will be undesignated.

As of , 2023, after giving effect to the automatic conversion of outstanding shares of our redeemable convertible preferred stock into an equivalent number of shares of our Class A Common Stock immediately prior to the closing of this offering, there were shares of Class A Common Stock outstanding, held of record by stockholders, and no shares of Class B Common Stock outstanding.

Class A Common Stock and Class B Common Stock

Our amended and restated certificate of incorporation will authorize the issuance of up to shares of our Class A Common Stock and shares of our Class B Common Stock. All outstanding shares of our Class A Common Stock and Class B Common Stock are validly issued, fully paid and nonassessable, and the shares of our Class A Common Stock to be issued in connection with this offering will be validly issued, fully paid and nonassessable.

Holders of our Class A Common Stock and Class B Common Stock have identical rights, provided that, (i) except as otherwise expressly provided in our amended and restated certificate of incorporation or as required by applicable law, on any matter that is submitted to a vote by our stockholders, holders of our Class A Common Stock are entitled to one vote per share of Class A Common Stock, and holders of our Class B Common Stock are not entitled to any votes per share of Class B Common Stock, including for the election of directors, and (ii) holders of our Class A Common Stock have no conversion rights, while holders of our Class B Common Stock shall have the right to convert each share of Class B Common Stock into one share of Class A Common Stock at such holder's election, provided that as a result of such conversion, such holder, together with its affiliates and any members of a Schedule 13(d) group with such holder, would not beneficially own in excess of 9.99% (the Beneficial Ownership Limitation) of our Class A Common Stock immediately prior to and following such conversion, unless otherwise expressly provided for in our amended and restated certificate of incorporation. However, the Beneficial Ownership Limitation may be increased or decreased to any other percentage (not to exceed 19.99%) designated by such holder of Class B Common Stock upon 61 days' notice to us.

Voting Rights

Each holder of our Class A Common Stock is entitled to one vote for each share on all matters submitted to a vote of the stockholders, including the election of directors and our Class B Common Stock is not entitled to any votes per share. The affirmative vote of holders of at least 66-2/3% of the voting power of all of the then-outstanding shares of Class A Common Stock, voting as a single class, will be required to amend certain provisions of our amended and restated certificate of incorporation, including provisions relating to amending our amended and restated bylaws, the classified board, the size of our board, removal of directors, director liability, vacancies on our board, special meetings, stockholder notices, actions by written consent and exclusive forum.

Economic Rights

Except as otherwise expressly provided in our amended and restated certificate of incorporation or required by applicable law, all shares of our Class A Common Stock and Class B Common Stock will have the same rights and privileges and rank equally, share ratably and be identical in all respects for all matters, including those described below.

Dividends. Subject to preferences that may be applicable to any then-outstanding preferred stock, holders of our Class A Common Stock and Class B Common Stock are entitled to receive ratably those dividends, if any, as may be declared from time to time by the board of directors out of legally available funds.

Liquidation Rights. In the event of our liquidation, dissolution or winding up, holders of our Class A Common Stock and Class B Common 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 preferred stock.

No Preemptive or Similar Rights

Holders of our Class A Common Stock and Class B Common Stock have no preemptive, conversion or subscription rights and there are no redemption or sinking fund provisions applicable to our Class A Common Stock and Class B Common Stock. The rights, preferences and privileges of the holders of our Class A Common Stock or Class B Common Stock are subject to, and may be adversely affected by, the right of the holders of shares of any series of preferred stock that we may designate in the future.

Fully Paid and Non-Assessable

In connection with this offering, our legal counsel will opine that the shares of our Class A Common Stock and Class B Common Stock to be issued under this offering will be fully paid and non-assessable.

Preferred Stock

As of , 2023, there were shares of redeemable convertible preferred stock outstanding, consisting of shares of Series A redeemable convertible preferred stock, shares of Series B redeemable convertible preferred stock and shares of Series C redeemable convertible preferred stock. All outstanding shares of redeemable convertible preferred stock will be converted into an equivalent number of shares of Class A Common Stock immediately prior to the closing of this offering.

Following the closing of this offering, our board of directors will have the authority under our amended and restated certificate of incorporation, without further action by our stockholders, to issue up to shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each such series, to fix the rights, preferences and privileges of the shares of each wholly unissued series and any qualifications, limitations or restrictions thereon, and to increase or decrease the number of shares of any such series, but not below the number of shares of such series then outstanding.

Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of our Class A Common Stock and Class B Common Stock. The purpose of authorizing our board of directors to issue preferred stock and determine its rights and preferences is to eliminate delays associated with a stockholder vote on specific issuances. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in control of us and may adversely affect the market price of our Class A Common Stock and the voting and other rights of the holders of our Class A Common Stock and Class B Common Stock. It is not possible to state the

actual effect of the issuance of any shares of preferred stock on the rights of holders of Class A Common Stock and Class B Common Stock until the board of directors determines the specific rights attached to that preferred stock.

We have no present plans to issue any shares of preferred stock following completion of this offering.

Stock Options and Restricted Stock Units; Shares Reserved for Future Issuance Under the 2023 Plan

As of , 2023, there were options to purchase shares of Class A Common Stock and RSUs representing shares of Class A Common Stock outstanding under our 2020 Plan. For additional information regarding the terms of our 2020 Plan, see the section titled "Executive Compensation—Equity Incentive Plans." In addition, as of , 2023, there were outstanding options to purchase shares of Class A Common Stock assumed in connection with the Acquisition. Following completion of this offering, shares of our Class A Common Stock will be reserved for future issuance under the 2023 Plan, which will become effective immediately prior to the execution of the underwriting agreement for this offering, as well as any future automatic annual increases in the number of shares of Class A Common Stock reserved for issuance under the 2023 Plan and any shares underlying outstanding stock awards granted under the 2020 Plan, that expire or are repurchased, forfeited, cancelled, or withheld. For additional information regarding terms of our equity incentive plans, see the section titled "Executive Compensation—Equity Benefit Plans."

Registration Rights

Upon the closing of this offering and subject to the lock-up agreements entered into in connection with this offering and federal securities laws, certain holders of shares of our Class A Common Stock, including those shares of our Class A Common Stock that will be issued upon the conversion of our redeemable convertible preferred stock in connection with this offering, will initially be entitled to certain rights with respect to registration of such shares under the Securities Act. These shares are referred to as registrable securities. The holders of these registrable securities possess registration rights pursuant to the terms of our amended and restated investors' rights agreement and are described in additional detail below. The registration of shares of our Class A Common Stock pursuant to the exercise of the registration rights described below would enable the holders to trade these shares without restriction under the Securities Act when the applicable registration statement is declared effective. We will pay the registration expenses, other than underwriting discounts, selling commissions and stock transfer taxes, and certain costs related to disbursement of counsel for holders of these registrable securities of the shares registered pursuant to the demand, piggyback and Form S-3 registrations described below.

Generally, in an underwritten offering, the managing underwriter, if any, has the right, subject to specified conditions and limitations, to limit the number of shares the holders may include. The demand, piggyback and Form S-3 registration rights described below will expire upon the earlier to occur of (i) five years after the closing of this offering, and (ii) with respect to any holder, (1) when such holder of registrable securities (together with its affiliates) holds less than 1% of our outstanding capital stock, and (2) when Rule 144 or another similar exemption under the Securities Act is available for the sale of all of such holder's shares, without limitation, during a three-month period.

Demand Registration Rights

Upon the closing of this offering, holders of an aggregate of shares of our registrable securities will be entitled to certain demand registration rights. At any time beginning 180 days after the closing of this offering, the holders of at least 30% of these shares then outstanding may request that we register all or a portion of their shares. We are not required to effect more than two registration statements which are declared or ordered effective. Such request for registration must cover shares with an anticipated aggregate offering size of at least $10.0 million, net of selling expenses. With certain exceptions, we are not required to effect the filing of a

registration statement (i) during the period starting with 60 days before our good faith estimate of the date of the filing of, and ending on a date 180 days following the effective date of a registration initiated by us, (ii) after we have effected two registration statements pursuant to such demand registration rights, or (iii) if the holders propose to dispose of the shares that may be immediately registered on Form S-3 pursuant to the Form S-3 registration rights described below.

Piggyback Registration Rights

Upon the closing of this offering, the holders of an aggregate of shares of our registrable securities will be entitled to certain piggyback registration rights. After this offering, in the event that we propose to register any of our securities under the Securities Act, either for our own account or for the account of other security holders, the holders of these shares will be entitled to certain piggyback registration rights allowing the holder to include their shares in such registration, subject to certain marketing and other limitations. The necessary percentage of holders waived their rights to notice of this offering and to include any registrable securities that they hold in this offering.

Form S-3 Registration Rights

Upon the closing of this offering, holders of an aggregate of shares of registrable securities will be entitled to certain Form S-3 registration rights. Holders of 30% of these shares then outstanding can make a request that we register their shares on Form S-3 if we are qualified to file a registration statement on Form S-3 and if the reasonably anticipated aggregate offering size would equal or exceed $5 million, net of selling expenses. We will not be required to effect (i) during the period that is 30 days before our good faith estimate of the date of fling of, and ending on the date that is 90 days after the effective date of, a registration initiated by us, provided that we are actively employing in good faith commercially reasonable efforts to cause such registration statement to become effective, or (ii) more than two registrations on Form S-3 within any 12-month period.

Anti-Takeover Provisions

Section 203 of the Delaware General Corporation Law

We are subject to Section 203 of the Delaware General Corporation Law, which prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years after the date that such stockholder became an interested stockholder, with the following exceptions:

- before such date, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;
- upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction began, excluding for purposes of determining the voting stock outstanding, but not the outstanding voting stock owned by the interested stockholder, those shares owned (i) by persons who are directors and also officers and (ii) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- on or after such date, the business combination is approved by the board of directors and authorized at an annual or special meeting of the stockholders, and not by written consent, by the affirmative vote of at least 66-2/3% of the outstanding voting stock that is not owned by the interested stockholder.

In general, Section 203 defines a “business combination” to include the following:

- any merger or consolidation involving the corporation or any direct or indirect majority-owned subsidiary of the corporation and the interested stockholder;

- any sale, lease, exchange, mortgage, pledge, transfer or other disposition of 10% or more of the assets of the corporation or of any direct or indirect majority-owned subsidiary involving the interested stockholder (in one transaction or a series of transactions);
- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation or by any direct or indirect majority-owned subsidiary of the corporation of any stock of the corporation or of such subsidiary to the interested stockholder;
- any transaction involving the corporation or any direct or indirect majority-owned subsidiary of the corporation that has the effect of increasing the proportionate share of the stock or any class or series of the corporation or any such subsidiary beneficially owned by the interested stockholder; or
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits by or through the corporation or any direct or indirect majority-owned subsidiary.

In general, Section 203 defines an "interested stockholder" as an entity or person who, together with the person's affiliates and associates, beneficially owns, or within three years prior to the time of determination of interested stockholder status did own, 15% or more of the outstanding voting stock of the corporation.

Certificate of Incorporation and Bylaws To Be in Effect Prior to the Closing of This Offering

Our amended and restated certificate of incorporation to be in effect immediately prior to the closing of this offering (our restated certificate) will provide for our board of directors to be divided into three classes with staggered three-year terms. Only one class of directors will be elected at each annual meeting of our stockholders, with the other classes continuing for the remainder of their respective three-year terms. Because our stockholders do not have cumulative voting rights, stockholders holding a majority of the shares of our Class A Common Stock outstanding will be able to elect all of our directors. Our restated certificate and our amended and restated bylaws to be effective upon the completion of this offering (our restated bylaws) will also provide that directors may be removed by the stockholders only for cause upon the vote of 66-2/3% or more of our outstanding Class A Common Stock. Furthermore, the authorized number of directors may be changed only by resolution of the board of directors, and vacancies and newly created directorships on the board of directors may, except as otherwise required by law or determined by the board and subject to the rights of any series of then-outstanding preferred stock, only be filled by a majority vote of the directors then serving on the board, even though less than a quorum.

Under our restated certificate and restated bylaws our stockholders will not have cumulative voting rights. Because of this, the holders of a majority of the shares of Class A Common Stock entitled to vote in any election of directors can elect all of the directors standing for election, if they should so choose.

Our restated certificate and restated bylaws will also provide that all stockholder actions must be effected at a duly called meeting of stockholders and will eliminate the right of stockholders to act by written consent without a meeting. Our restated bylaws will also provide that only our Chairman of the board, Chief Executive Officer or the board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors may call a special meeting of stockholders.

Our restated bylaws will also provide that stockholders seeking to present proposals before a meeting of stockholders to nominate candidates for election as directors at a meeting of stockholders must provide timely advance notice in writing, and will specify requirements as to the form and content of a stockholder's notice.

Our restated certificate and restated bylaws will provide that the stockholders cannot amend many of the provisions described above except by a vote of 66-2/3% or more of our outstanding Class A Common Stock.

As described in the subsection titled "—Preferred Stock" above, our restated certificate will give our board of directors the authority, without further action by our stockholders, to issue up to shares of preferred stock in one or more series, with any rights, preferences and privileges as they may designate, including the right to approve an acquisition or other change in control.

The combination of these provisions will make it more difficult for our existing stockholders to replace our board of directors as well as for another party to obtain control of us by replacing our board of directors. Since our board of directors has the power to retain and discharge our officers, these provisions could also make it more difficult for existing stockholders or another party to effect a change in management. In addition, the authorization of undesignated preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change our control.

These provisions are intended to enhance the likelihood of continued stability in the composition of our board of directors and its policies and to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to reduce our vulnerability to hostile takeovers and to discourage certain tactics that may be used in proxy fights. However, such provisions could have the effect of discouraging others from making tender offers for our shares and may have the effect of delaying changes in our control or management. As a consequence, these provisions may also inhibit fluctuations in the market price of our stock that could result from actual or rumored takeover attempts. We believe that the benefits of these provisions, including increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure our company, outweigh the disadvantages of discouraging takeover proposals, because negotiation of takeover proposals could result in an improvement of their terms.

Choice of Forum

Our amended and restated certificate of incorporation will provide that the Court of Chancery of the state of Delaware will be the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law:

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

The provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims.

To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation will also provide that unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act.

While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions

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 lawsuits against us and our directors, officers and other employees. If a court were to find either exclusive-forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving the dispute in other jurisdictions, all of which could seriously harm our business.

Our amended and restated certificate of incorporation will 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, subject to and contingent upon a final adjudication in the State of Delaware of the enforceability of such exclusive forum provision.

Limitations on Liability and Indemnification

See the section titled "Executive Compensation—Limitations on Liability and Indemnification."

Exchange Listing

Our Class A Common Stock is currently not listed on any securities exchange. We intend to apply to have Class A Common Stock approved for listing on The Nasdaq Global Market under the symbol "XLRN." Our Class B Common Stock will not be listed on any securities exchange.

Transfer Agent and Registrar

On the closing of this offering, the transfer agent and registrar for our Class A Common Stock will be . The transfer agent's address is .

SHARES ELIGIBLE FOR FUTURE SALE

Before the closing of this offering, there has been no public market for our Class A Common Stock. Future sales of substantial amounts of our Class A Common Stock, including shares issued on the exercise of outstanding options, the settlement of RSUs, or upon the conversion of our Class B Common Stock, in the public market after this offering, or the possibility of these sales or issuances occurring, could adversely affect the prevailing market price for our Class A Common Stock or impair our ability to raise equity capital.

Upon the completion of this offering and assuming the automatic conversion of shares of our redeemable convertible preferred stock as of , 2023 into an equivalent number of shares of our Class A Common Stock and the issuance of shares of our Class A Common Stock upon vesting and settlement of RSUs at the completion of this offering, we will have an aggregate of shares of our Class A Common Stock outstanding (or shares of Class A Common Stock if the underwriters exercise in full their option to purchase additional shares) and no shares of Class B Common Stock outstanding. Of these shares, all of the Class A Common Stock sold in this offering, as well as any shares sold upon the exercise of the underwriters' option to purchase additional shares of Class A Common Stock, will be freely tradable in the public market without restriction or further registration under the Securities Act, unless these shares are held by "affiliates," as that term is defined in Rule 144 under the Securities Act.

The remaining shares of Class A Common Stock will be, and shares of Class A Common Stock subject to outstanding RSUs will be on issuance, "restricted securities," as that term is defined in Rule 144. These restricted securities are eligible for public sale only if they are registered under the Securities Act or if they qualify for an exemption from registration under Rules 144 or 701 under the Securities Act, which are summarized below. Restricted securities may also be sold outside of the United States to non-U.S. persons in accordance with Rule 904 of Regulation S.

Subject to the lock-up agreements described below and the provisions of Rule 144 or Regulation S under the Securities Act, as well as our insider trading policy, these restricted securities will be available for sale in the public market after the date of this prospectus.

Rule 144

In general, under Rule 144 as currently in effect, once we have been subject to public company reporting requirements of Section 13 or Section 15(d) of the Exchange Act for at least 90 days, an eligible stockholder is entitled to sell such shares without complying with the manner of sale, volume limitation, or notice provisions of Rule 144, subject to compliance with the public information requirements of Rule 144. To be an eligible stockholder under Rule 144, such stockholder must not be deemed to have been one of our affiliates for purposes of the Securities Act at any time during the 90 days preceding a sale and must have beneficially owned the shares proposed to be sold for at least six months, including the holding period of any prior owner other than our affiliates. If such a person has beneficially owned the shares proposed to be sold for at least one year, including the holding period of any prior owner other than our affiliates, then such person is entitled to sell such shares without complying with any of the requirements of Rule 144, subject to the lock-up agreements described below.

In general, under Rule 144, as currently in effect, our affiliates or persons selling shares on behalf of our affiliates are entitled to sell shares on expiration of the lock-up agreements described below. Beginning 90 days after the date of this prospectus, within any three-month period, such stockholders may sell a number of shares that does not exceed the greater of:

- 1% of the number of shares of Class A Common Stock then outstanding, which will equal approximately shares immediately after this offering, assuming no exercise of the underwriters' option to purchase additional shares of Class A Common Stock from us; or

- the average weekly trading volume of our Class A Common Stock on The Nasdaq Global Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

Sales under Rule 144 by our affiliates or persons selling shares on behalf of our affiliates are also subject to certain manner of sale provisions and notice requirements and to the availability of current public information about us.

Rule 701

Rule 701 of the Securities Act (Rule 701) generally allows a stockholder who was issued shares under a written compensatory plan or contract and who is not deemed to have been an affiliate of our company during the immediately preceding 90 days, to sell these shares in reliance on Rule 144, but without being required to comply with the public information, holding period, volume limitation, or notice provisions of Rule 144. Rule 701 also permits affiliates of our company to sell their Rule 701 shares under Rule 144 without complying with the holding period requirements of Rule 144. All holders of Rule 701 shares, however, are required by that rule to wait until 90 days after the date of this prospectus before selling those shares under Rule 701, subject to the lock-up agreements described below.

Form S-8 Registration Statements

We intend to file one or more registration statements on Form S-8 under the Securities Act with the SEC to register the offer and sale of shares of our Class A Common Stock that are issuable upon exercise of outstanding stock options and shares of our Class A Common Stock reserved for future issuance under the 2023 Plan and ESPP. These registration statements will become effective immediately on filing. Shares covered by these registration statements will then be eligible for sale in the public markets, subject to vesting restrictions, any agreements described below, and Rule 144 limitations applicable to affiliates.

Lock-Up Arrangements

We, and all of our directors, officers and the holders of substantially all of our Class A Common Stock and securities exercisable for or convertible into our Class A Common Stock (including shares of our Class B Common Stock), have agreed with the underwriters that, until 180 days after this offering, we and they will not, subject to certain exceptions, without the prior written consent of the representatives of the underwriters, directly or indirectly, offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend or otherwise transfer or dispose of any of our shares of Class A Common Stock, or any securities convertible into or exercisable or exchangeable for shares of our Class A Common Stock, or enter into any hedging, swap or any other agreement or any transaction that transfers, in whole or in part, directly or indirectly, the economic consequence of ownership of the securities, whether any such swap or transaction is to be settled by delivery of our Class A Common Stock or other securities, in cash or otherwise. These agreements are described in more detail in the section titled “Underwriters.” The representatives of the underwriters may, in their sole discretion, release any of the securities subject to these lock-up agreements at any time.

In addition to the restrictions contained in the lock-up agreements described above, we have entered into agreements with certain of our security holders, that contain market stand-off provisions or incorporate market stand-off provisions from our equity incentive plan imposing restrictions on the ability of such security holders to offer, sell or transfer our equity securities for a period of 180 days following the date of this prospectus.

Registration Rights

Upon the closing of this offering, pursuant to our amended and restated investors’ rights agreement, the holders of shares of our Class A Common Stock, or their transferees, will be entitled to certain rights with respect to the registration of the offer and sale of their shares under the Securities Act, subject to the terms

of the lock-up agreements described under the section titled "—Lock-Up Arrangements" above. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act immediately on the effectiveness of the registration. Any sales of securities by these stockholders could adversely affect the trading price of our Class A Common Stock. See the sub-section titled "Description of Capital Stock—Registration Rights" for additional information.

MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS OF OUR CLASS A COMMON STOCK

The following is a summary of the material U.S. federal income tax consequences to non-U.S. holders (as defined below) of the purchase, ownership and disposition of our Class A Common Stock issued pursuant to this offering. This discussion is not a complete analysis of all potential U.S. federal income tax consequences relating thereto, does not address the potential application of the Medicare contribution tax on net investment income, the alternative minimum tax or the special tax accounting rules under Section 451(b) of the Internal Revenue Code of 1986, as amended (the Code), and does not address any estate or gift tax consequences or any tax consequences arising under any state, local or foreign tax laws, or any other U.S. federal tax laws. This discussion is based on the Code, Treasury Regulations promulgated thereunder, judicial decisions and published rulings and administrative pronouncements of the Internal Revenue Service (the IRS), all as in effect as of the date hereof. These authorities are subject to differing interpretations and may change, possibly retroactively, resulting in U.S. federal income tax consequences different from those discussed below. We have not requested a ruling from the 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 discussion is limited to non-U.S. holders who purchase our Class A Common Stock pursuant to this offering and who hold our Class A Common Stock as a "capital asset" within the meaning of Section 1221 of the Code (generally, property held for investment). This discussion does not address all of the U.S. federal income tax consequences that may be relevant to a non-U.S. holder in light of such non-U.S. holder's particular circumstances. This discussion also does not consider any specific facts or circumstances that may be relevant to non-U.S. holders subject to special rules under the U.S. federal income tax laws, including:

- certain former citizens or long-term residents of the United States;
- partnerships or other entities or arrangements treated as partnerships, pass-throughs, or disregarded entities for U.S. federal income tax purposes (and investors therein);
- "controlled foreign corporations;"
- "passive foreign investment companies;"
- corporations that accumulate earnings to avoid U.S. federal income tax;
- banks, financial institutions, investment funds, insurance companies, brokers, dealers or traders in securities;
- tax-exempt organizations and governmental organizations;
- tax-qualified retirement plans;
- persons who received our Class A Common Stock as compensation;
- qualified foreign pension funds as defined in Section 897(l)(2) of the Code and entities all of the interests of which are held by qualified foreign pension funds;
- persons that own or have owned, actually or constructively, more than 5% of our Class A Common Stock;
- persons who have elected to mark securities to market; and
- persons holding our Class A Common Stock as part of a hedging or conversion transaction or straddle, or a constructive sale, or other risk reduction strategy or integrated investment.

If an entity or arrangement that is classified as a partnership for U.S. federal income tax purposes holds our Class A Common Stock, the U.S. federal income tax treatment of a partner in the partnership will generally depend on the status of the partner, the activities of the partnership and certain determinations made at the partner level. Partnerships holding our Class A Common Stock and the partners in such partnerships are urged to consult their tax advisors about the particular U.S. federal income tax consequences to them of holding and disposing of our Class A Common Stock.

THIS DISCUSSION IS FOR INFORMATIONAL PURPOSES ONLY AND IS NOT TAX ADVICE. PROSPECTIVE INVESTORS SHOULD CONSULT THEIR TAX ADVISORS REGARDING THE PARTICULAR U.S. FEDERAL INCOME TAX CONSEQUENCES TO THEM OF ACQUIRING, OWNING AND DISPOSING OF OUR CLASS A COMMON STOCK, AS WELL AS ANY TAX CONSEQUENCES ARISING UNDER ANY STATE, LOCAL OR FOREIGN TAX LAWS AND ANY OTHER U.S. FEDERAL TAX LAWS.

Definition of Non-U.S. Holder

For purposes of this discussion, a non-U.S. holder is any beneficial owner of our Class A Common Stock that is not a "U.S. person" or a partnership (including any entity or arrangement treated as a partnership) for U.S. federal income tax purposes. A U.S. person is any person that, for U.S. federal income tax purposes, is or is treated as any of the following:

- an individual who is a citizen or resident of the United States;
- a corporation created or organized under the laws of the United States, any state thereof or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust (i) whose administration is subject to the primary supervision of a U.S. court and which has one or more U.S. persons who have the authority to control all substantial decisions of the trust or (ii) that has a valid election in effect under applicable Treasury Regulations to be treated as a U.S. person.

Distributions on Our Class A Common Stock

As described in the section titled "Dividend Policy," we do not anticipate declaring or paying, in the foreseeable future, any dividends on our capital stock. However, if we distribute cash or other property on our Class A Common Stock, such distributions 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. Any portion of a distribution that exceeds our current and accumulated earnings and profits will constitute a return of capital and will first be applied against and reduce a holder's tax basis in our Class A Common Stock, but not below zero. Any amount distributed in excess of basis will be treated as gain realized on the sale or other disposition of our Class A Common Stock and will be treated as described in the subsection titled "—Gain on Disposition of Our Class A Common Stock" below.

Subject to the discussion below regarding effectively connected income, backup withholding and FATCA (as defined below), dividends paid to a non-U.S. holder of our Class A Common Stock generally will be subject to U.S. federal withholding tax at a rate of 30% of the gross amount of the dividends or such lower rate specified by an applicable income tax treaty. To receive the benefit of a reduced treaty rate, a non-U.S. holder must furnish us or our withholding agent with a valid IRS Form W-8BEN (in the case of individuals) or IRS Form W-8BEN-E (in the case of entities), or other appropriate form, certifying such holder's qualification for the reduced rate. This certification must be provided to us or our withholding agent before the payment of dividends and must be updated periodically. If the non-U.S. holder holds our Class A 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 us or our withholding agent, either directly or through other intermediaries.

If a non-U.S. holder holds our Class A Common Stock in connection with the conduct of a trade or business in the United States, and dividends paid on our Class A Common Stock are effectively connected with such holder's U.S. trade or business (and if required by an applicable tax treaty, are attributable to such holder's permanent establishment or fixed base in the United States), the non-U.S. holder generally will be exempt from U.S. federal withholding tax. To claim the exemption, the non-U.S. holder generally must furnish a valid IRS Form W-8ECI (or applicable successor form) to the applicable withholding agent.

However, any such effectively connected dividends paid on our Class A Common Stock generally will be subject to U.S. federal income tax on a net income basis at the regular U.S. federal income tax rates in the same manner as if such holder were a resident of the United States. A non-U.S. holder that is a foreign corporation also may be subject to an additional branch profits tax equal to 30% (or such lower rate specified by an applicable income tax treaty) of its effectively connected earnings and profits for the taxable year, as adjusted for certain items.

Non-U.S. holders that do not provide the required certification on a timely basis, but that qualify for a reduced treaty rate, may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS. Non-U.S. holders should consult their tax advisors regarding any applicable income tax treaties that may provide for different rules.

Gain on Disposition of Our Class A Common Stock

Subject to the discussions below regarding backup withholding and FATCA (as defined below), a non-U.S. holder generally will not be subject to U.S. federal income tax on any gain realized on the sale or other disposition of our Class A Common Stock, unless:

- the gain is effectively connected with the non-U.S. holder's conduct of a trade or business in the United States and, if required by an applicable income tax treaty, is attributable to a permanent establishment or fixed base maintained by the non-U.S. holder in the United States;
- the non-U.S. holder is a nonresident alien individual present in the United States for 183 days or more during the taxable year of the disposition, and certain other requirements are met; or
- we are or become a United States real property holding corporation (a USRPHC) for U.S. federal income tax purposes at any time within the shorter of the five-year period preceding the disposition or the non-U.S. holder's holding period for our Class A Common Stock, and our Class A Common Stock is not regularly traded on an established securities market during the calendar year in which the sale or other disposition occurs.

Determining 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 other trade or business assets and our foreign real property interests. We believe that we are not currently and we do not anticipate becoming a USRPHC for U.S. federal income tax purposes, although there can be no assurance we will not in the future become a USRPHC.

Gain described in the first bullet point above generally will be subject to U.S. federal income tax on a net income basis at the regular U.S. federal income tax rates in the same manner as if such holder were a resident of the United States. A non-U.S. holder that is a foreign corporation also may be subject to an additional branch profits tax equal to 30% (or such lower rate specified by an applicable income tax treaty) of its effectively connected earnings and profits for the taxable year, as adjusted for certain items. A non-U.S. holder described in the second bullet point above will be subject to U.S. federal income tax at a flat 30% rate (or such lower rate specified by an applicable income tax treaty), on gain realized upon the sale or other taxable disposition of our Class A Common Stock which may be offset by certain U.S.-source capital losses (even though the individual is not considered a resident of the United States), provided that the non-U.S. holder has timely filed U.S. federal income tax returns with respect to such losses. If we are or become a USRPHC during the period described in the third bullet point above and our Class A Common Stock is not regularly traded for purposes of the relevant rules, gain arising from the sale or other taxable disposition of our Class A Common Stock by a non-U.S. holder will generally be subject to U.S. federal income tax in the same manner as gain that is effectively connected with the conduct of a U.S. trade or business, except that the branch profits tax generally will not apply.

Non-U.S. holders should consult their tax advisors regarding any applicable income tax treaties that may provide for different rules.

Information Reporting and Backup Withholding

Annual reports are required to be filed with the IRS and provided to each non-U.S. holder indicating the amount of distributions on our Class A Common Stock paid to such holder and the amount of any tax withheld with respect to those distributions. These information reporting requirements apply even if no withholding was required because the distributions were effectively connected with the holder's conduct of a U.S. trade or business, or withholding was reduced or eliminated by an applicable income tax treaty. This information also may be made available under a specific treaty or agreement with the tax authorities in the country in which the non-U.S. holder resides or is established. Backup withholding, currently at a 24% rate, generally will not apply to payments to a non-U.S. holder of dividends on or the gross proceeds of a disposition of our Class A Common Stock provided the non-U.S. holder furnishes the required certification for its non-U.S. status, such as by providing a valid IRS Form W-8BEN, IRS Form W-8BEN-E or IRS Form W-8ECI, or certain other requirements are met, and if the payor does not have actual knowledge, or reason to know, that the holder is a U.S. person who is not an exempt recipient.

Backup withholding is not an additional tax. If any amount is withheld under the backup withholding rules, the non-U.S. holder should consult with a U.S. tax advisor regarding the possibility of and procedure for obtaining a refund or a credit against the non-U.S. holder's U.S. federal income tax liability, if any.

Withholding on Payment to Certain Foreign Accounts or Entities

Sections 1471 through 1474 of the Code (commonly referred to as FATCA), impose a U.S. federal withholding tax of 30% on certain payments made to a "foreign financial institution" (as specially defined under these rules) unless such institution enters into an agreement with the U.S. government to withhold on certain payments and to collect and provide to the U.S. tax authorities substantial information regarding certain 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 an exemption applies. FATCA also generally will impose a U.S. federal withholding tax of 30% on certain payments made to a non-financial foreign entity unless such entity provides the withholding agent a certification identifying certain direct and indirect U.S. owners of the entity or an exemption applies. An intergovernmental agreement between the United States and an applicable foreign country may modify these requirements. Under certain circumstances, a non-U.S. holder might be eligible for refunds or credits of such taxes. FATCA currently applies to dividends paid on our Class A Common Stock and subject to the proposed Treasury Regulations described below, also applies to payments of gross proceeds from the sale or other disposition of our Class A Common Stock. The U.S. Treasury Department has released proposed Treasury Regulations under FATCA, which, if finalized in their present form, would eliminate the federal withholding tax of 30% applicable to gross proceeds of a sale or other disposition of our Class A Common Stock. In the preamble to such proposed Treasury Regulations, the U.S. Treasury Department stated that taxpayers generally may rely on the proposed Treasury Regulations until final regulations are issued.

Prospective investors are encouraged to consult with their own tax advisors regarding the possible implications of FATCA on their investment in our Class A Common Stock.

UNDERWRITERS

Under the terms and subject to the conditions in an underwriting agreement dated the date of this prospectus, the underwriters named below, for whom Morgan Stanley & Co. LLC, Jefferies LLC, Cowen and Company, LLC and Piper Sandler & Co. are acting as representatives, have severally agreed to purchase, and we have agreed to sell to them, severally, the number of shares of Class A Common Stock indicated below:

Name	Number of Shares
Morgan Stanley & Co. LLC	
Jefferies LLC	
Cowen and Company, LLC	
Piper Sandler & Co.	
Total	

The underwriters and the representatives are collectively referred to as the "underwriters" and the "representatives," respectively. The underwriters are offering the shares of Class A Common Stock subject to their acceptance of the shares from us and subject to prior sale. The underwriting agreement provides that the obligations of the several underwriters to pay for and accept delivery of the shares of Class A Common Stock offered by this prospectus are subject to the approval of certain legal matters by their counsel and to certain other conditions. The underwriters are obligated to take and pay for all of the shares of Class A Common Stock offered by this prospectus if any such shares are taken. However, the underwriters are not required to take or pay for the shares covered by the underwriters' over-allotment option described below.

The underwriters initially propose to offer part of the shares of Class A Common Stock directly to the public at the offering price listed on the cover page of this prospectus and part to certain dealers at a price that represents a concession not in excess of $ per share under the public offering price. After the initial offering of the shares of Class A Common Stock, the offering price and other selling terms may from time to time be varied by the representatives.

We have granted to the underwriters an option, exercisable for 30 days from the date of this prospectus, to purchase up to additional shares of Class A Common Stock at the public offering price listed on the cover page of this prospectus, less underwriting discounts and commissions. The underwriters may exercise this option solely for the purpose of covering over-allotments, if any, made in connection with the offering of the shares of Class A Common Stock offered by this prospectus. To the extent the option is exercised, each underwriter will become obligated, subject to certain conditions, to purchase about the same percentage of the additional shares of Class A Common Stock as the number listed next to the underwriter's name in the preceding table bears to the total number of shares of Class A Common Stock listed next to the names of all underwriters in the preceding table.

The following table shows the per share and total public offering price, underwriting discounts and commissions, and proceeds before expenses to us. These amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase up to an additional shares of Class A Common Stock.

		Total	
	Per Share	No Exercise	Full Exercise
Public offering price	$	$	$
Underwriting discounts and commissions to be paid by us	$	$	$
Proceeds, before expenses, to us	$	$	$

The estimated offering expenses payable by us, exclusive of underwriting discounts and commissions, are approximately $. We have agreed to reimburse the underwriters for expenses relating to clearance of this offering with the Financial Industry Regulatory Authority up to $.

The underwriters have informed us that they do not intend sales to discretionary accounts to exceed 5% of the total number of shares of Class A Common Stock offered by them.

We intend to apply to list our Class A Common Stock on the Nasdaq Global Market under the trading symbol "XLRN."

In connection with this offering, we and all of our directors, officers and the holders of substantially all of our outstanding Class A Common Stock and securities directly or indirectly convertible into or exchangeable or exerciseable for our Class A Common Stock entered into lock-up agreements with the underwriters agreeing that, subject to certain exceptions, without the prior written consent of the representatives on behalf of the underwriters, we and they will not, during the period ending 180 days after the date of this prospectus (the restricted period):

(i) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, make any short sale, or otherwise transfer or dispose of, directly or indirectly, any shares of our Class A Common Stock and securities directly or indirectly convertible into or exchangeable or exercisable for our Class A Common Stock;

(ii) enter into any swap, hedging transaction, or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of our Class A Common Stock, whether any such transaction described above is to be settled by delivery of our Class A Common Stock or such other securities, in cash or otherwise;

(iii) publicly disclose the intention to take any of the actions restricted by clause (i) or (ii) above; or

(iv) make any demand for, or exercise any right with respect to, the registration of any shares of our Class A Common Stock or any security convertible into or exercisable or exchangeable for our Class A Common Stock.

With respect to us, the restrictions described in the immediately preceding paragraph to do not apply to:

(i) the sale of shares of Class A Common Stock to the underwriters;

(ii) the issuance by the Company of shares of Class A Common Stock upon the exercise of an option or a warrant or the conversion of a security outstanding on the date of this prospectus; or

(iii) facilitating the establishment of a trading plan on behalf of a stockholder, officer or director of the Company pursuant to Rule 10b5-1 under the Exchange Act for the transfer of shares of Class A Common Stock, provided that (a) such plan does not provide for the transfer of Class A Common Stock during the restricted period and (b) to the extent a public announcement or filing under the Exchange Act, if any, is required or voluntarily made regarding the establishment of such plan, such announcement or filing shall include a statement to the effect that no transfer of Class A Common Stock may be made under such plan during the restricted period.

With respect to our directors, officers and the holders of substantially all of our outstanding Class A Common Stock and securities directly or indirectly convertible into or exchangeable or exerciseable for our Class A Common Stock, the restrictions described above to do not apply to:

(i) transactions relating to shares of Class A Common Stock acquired in this offering or in open market transactions after the completion of this offering, provided that no filing under Section 16(a) of the Exchange Act shall be required or voluntarily made during the restricted period in connection with such transactions;

(ii) transfers of shares of Class A Common Stock or securities directly or indirectly convertible into or exchangeable or exerciseable for our Class A Common Stock (a) as a bona fide gift, (b) to an immediate family member or to any trust for the direct or indirect benefit of the lock-up party or an

immediate family member of the lock-up party, (c) to any corporation, partnership, limited liability company, investment fund, trust or other entity of which the lock-up party and the immediate family of the lock-up party are the legal and beneficial owner of all of the outstanding equity securities or similar interests, or (d) by will, other testamentary document or intestate succession to the legal representative, heir, beneficiary or an immediate family member of the lockup party; provided that in the case of any transfer or distribution pursuant to this clause (ii), (1) such transfer shall not involve a disposition for value, (2) each donee, distributee or transferee shall sign and deliver a lock-up agreement to the underwriters and (3) other than in the case of preceding clause (d), no filing under Section 16(a) of the Exchange Act reporting a reduction in beneficial ownership shall be required or voluntarily made during the restricted period;

(iii) if the lock-up party is a corporation, partnership, limited liability company, trust or other business entity, (a) transfers or distributions of shares of Class A Common Stock or securities directly or indirectly convertible into or exchangeable or exerciseable for our Class A Common Stock to current or former general or limited partners, managers or members, stockholders, other equity holders or direct or indirect affiliates (within the meaning of Rule 405 under the Securities Act) of the lock-up party, or to the estates of any of the foregoing or (b) transfers or distributions to any investment fund or other entity controlling, controlled by, managing or managed by or under common control with the lock-up party or affiliates of the lock-up party, provided that, in the case of any transfer or distribution pursuant to this clause (iii), (1) each transferee or distributee shall sign and deliver a lock-up agreement to the underwriters, (2) no filing under the Exchange Act reporting a reduction in beneficial ownership shall be required or voluntarily made during the restricted period, and (3) such transfer shall not involve a disposition for value;

(iv) the transfer of shares of Class A Common Stock and securities directly or indirectly convertible into or exchangeable or exerciseable for our Class A Common Stock to the Company to satisfy any tax, including estimated tax, remittance, or other payment obligations of the lock-up party arising in connection with a vesting event of the Company's securities or the payment due for the exercise of options (including a transfer to the Company for the "net" or "cashless" exercise of options) or other rights to purchase securities of the Company; provided, that any securities received upon such vesting or exercise shall be subject to the terms of the lock-up agreement; and provided further, that to the extent a filing under Section 16(a) of the Exchange Act is required during the restricted period as a result of transfers made pursuant to this clause (iv), such filing shall clearly indicate the circumstances;

(v) the establishment or amendment of a trading plan pursuant to Rule 10b5-1 under the Exchange Act, provided that (a) such plan does not provide for the transfer of Class A Common Stock during the restricted period, and (b) to the extent a public announcement or filing under the Exchange Act is required of or voluntarily made by or on behalf of the lock-up party or the Company regarding the establishment of such plan during the restricted Period, such announcement or filing shall include a statement to the effect that no transfer of shares may be made under such plan during the restricted period;

(vi) the transfer of shares of Class A Common Stock or securities directly or indirectly convertible into or exchangeable or exerciseable for our Class A Common Stock that occurs by operation of law pursuant to a qualified domestic order or in connection with a divorce settlement or other court order, provided that (a) the transferee shall sign and deliver a lock-up agreement to the underwriters, and (b) any filing required under Section 16(a) of the Exchange Act during the restricted period shall clearly indicate the circumstances;

(vii) transfers to the Company in connection with the repurchase of securities in connection with the termination of the lock-up party's employment with us; provided that no public disclosure or filing under Section 16(a) of the Exchange Act shall be required or shall be voluntarily made during the restricted period;

(viii) the transfer of securities pursuant to a bona fide third- party tender offer, merger, consolidation or other similar transaction that is approved by the Board of Directors of the Company, provided that, in the event that the tender offer, merger, consolidation or other such transaction is not completed, the securities owned by the lock-up party shall remain subject to the restrictions set forth above;

(ix) certain additional transfers to be agreed upon prior to the completion of this offering with the representatives on behalf of the Underwriters; or

(x) transfers with the prior written consent of the representatives on behalf of the Underwriters.

The representatives, in their sole discretion, may release the Class A Common Stock and other securities subject to the lock-up agreements described above in whole or in part at any time.

In order to facilitate the offering of the Class A Common Stock, the underwriters may engage in transactions that stabilize, maintain or otherwise affect the price of the Class A Common Stock. Specifically, the underwriters may sell more shares than they are obligated to purchase under the underwriting agreement, creating a short position. A short sale is covered if the short position is no greater than the number of shares available for purchase by the underwriters under the over-allotment option. The underwriters can close out a covered short sale by exercising the over-allotment option or purchasing shares in the open market. In determining the source of shares to close out a covered short sale, the underwriters will consider, among other things, the open market price of shares compared to the price available under the over-allotment option. The underwriters may also sell shares in excess of the over-allotment option, creating a naked short position. 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 Class A Common Stock in the open market after pricing that could adversely affect investors who purchase in this offering. As an additional means of facilitating this offering, the underwriters may bid for, and purchase, shares of Class A Common Stock in the open market to stabilize the price of the Class A Common Stock. These activities may raise or maintain the market price of the Class A Common Stock above independent market levels or prevent or retard a decline in the market price of the Class A Common Stock. The underwriters are not required to engage in these activities and may end any of these activities at any time.

We and the underwriters have agreed to indemnify each other against certain liabilities, including liabilities under the Securities Act.

A prospectus in electronic format may be made available on websites maintained by one or more underwriters, or selling group members, if any, participating in this offering. The representatives may agree to allocate a number of shares of Class A Common Stock to underwriters for sale to their online brokerage account holders. Internet distributions will be allocated by the representatives to underwriters that may make Internet distributions on the same basis as other allocations.

The underwriters and their respective 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. Certain of the underwriters and their respective affiliates have, from time to time, performed, and may in the future perform, various financial advisory and investment banking services for us, for which they received or will receive customary fees and expenses.

In addition, in the ordinary course of their various business activities, the underwriters and their respective 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 may at any time hold long and short positions in such securities and instruments. Such investment and securities activities may involve our securities and instruments. The underwriters and their respective affiliates may also make investment recommendations 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 or short positions in such securities and instruments.

Pricing of the Offering

Prior to this offering, there has been no public market for our Class A Common Stock. The initial public offering price was determined by negotiations between us and the representatives. Among the factors considered in determining the initial public offering price were our future prospects and those of our industry in general, our sales, earnings and certain other financial and operating information in recent periods, and the price-earnings ratios, price-sales ratios, market prices of securities, and certain financial and operating information of companies engaged in activities similar to ours.

Selling Restrictions

Notice to Prospective Investors in the European Economic Area

In relation to each Member State of the European Economic Area, or, each a Member State, no shares of Class A Common Stock have been offered or will be offered pursuant to the offering to the public in that Member State prior to the publication of a prospectus in relation to the shares of Class A Common Stock which has been approved by the competent authority in that Member State or, where appropriate, approved in another Member State and notified to the competent authority in that Member State, all in accordance with the Prospectus Regulation, except that offers of Class A Common Stock shares may be made to the public in that Member State at any time under the following exemptions under the Prospectus Regulation:

(i) to any legal entity which is a qualified investor as defined under the Prospectus Regulation;

(ii) to fewer than 150 natural or legal persons (other than qualified investors as defined under the Prospectus Regulation), subject to obtaining the prior consent of the underwriters; or

(iii) in any other circumstances falling within Article 1(4) of the Prospectus Regulation,

provided that no such offer of shares of Class A Common Stock shall require us or any underwriter to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation and each person who initially acquires any shares or to whom any offer is made will be deemed to have represented, acknowledged and agreed to and with each of the underwriters and us that it is a "qualified investor" within the meaning of Article 2(e) of the Prospectus Regulation. In the case of any shares of Class A Common Stock being offered to a financial intermediary as that term is used in the Prospectus Regulation, each such financial intermediary will be deemed to have represented, acknowledged and agreed that the shares of Class A Common Stock acquired by it in the offer have not been acquired on a non-discretionary basis on behalf of, nor have they been acquired with a view to their offer or resale to, persons in circumstances which may give rise to an offer of any shares of Class A Common Stock to the public other than their offer or resale in a Member State to qualified investors as so defined or in circumstances in which the prior consent of the underwriters have been obtained to each such proposed offer or resale.

For the purposes of this provision, the expression an "offer to the public" in relation to shares in any Member State means the communication in any form and by any means of sufficient information on the terms of the offer and any shares of Class A Common Stock to be offered so as to enable an investor to decide to purchase or subscribe for any shares of Class A Common Stock, and the expression "Prospectus Regulation" means Regulation (EU) 2017/1129.

Notice to Prospective Investors in the United Kingdom

No shares of Class A Common Stock 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 Class A Common Stock which has been approved by the Financial Conduct Authority, except that the Class A Common Stock may be offered to the public in the United Kingdom at any time:

(i) to any legal entity which is a qualified investor as defined under Article 2 of the U.K. Prospectus Regulation;

(ii) to fewer than 150 natural or legal persons (other than qualified investors as defined under Article 2 of the U.K. Prospectus Regulation), subject to obtaining the prior consent of the representatives of the underwriters for any such offer; or

(iii) in any other circumstances falling within Section 86 of the FSMA,

provided that no such offer of the Class A Common Stock shall require our company or any underwriter to publish a prospectus pursuant to Section 85 of the FSMA or supplement a prospectus pursuant to Article 23 of the U.K. Prospectus Regulation. For the purposes of this provision, the expression an "offer to the public" in relation to the Class A Common Stock 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 of Class A Common Stock to be offered so as to enable an investor to decide to purchase or subscribe for any shares of Class A Common Stock and the expression "U.K. Prospectus Regulation" means Regulation (EU) 2017/1129 as it forms part of domestic law by virtue of the European Union (Withdrawal) Act 2018.

In addition, in the United Kingdom, this document is being distributed only to, and is directed only at, and any offer subsequently made may only be directed at persons who are "qualified investors" (as defined in the Prospectus Regulation) (i) who have professional experience in matters relating to investments falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended, or the Order, and/or (ii) who are high net worth companies (or persons to whom it may otherwise be lawfully communicated) falling within Article 49(2)(a) to (d) of the Order, or, all such persons together being referred to as relevant persons, or otherwise in circumstances which have not resulted and will not result in an offer to the public of the shares in the United Kingdom within the meaning of the Financial Services and Markets Act 2000.

Any person in the United Kingdom that is not a relevant person should not act or rely on the information included in this document or use it as basis for taking any action. In the United Kingdom, any investment or investment activity that this document relates to may be made or taken exclusively by relevant persons.

Notice to Prospective Investors in Canada

The Class A Common Stock may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 Prospectus Exemptions or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103 Registration Requirements, Exemptions and Ongoing Registrant Obligations. Any resale of the Class A Common Stock must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) 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 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.

Pursuant to section 3A.3 of National Instrument 33-105 Underwriting Conflicts (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

Notice to Prospective Investors in Switzerland

The Class A Common Stock may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange, or SIX, or on any other stock exchange or regulated trading facility in Switzerland. This

document does not constitute a prospectus within the meaning of, and 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 document nor any other offering or marketing material relating to the Class A Common Stock or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering or marketing material relating to the offering, us or the Class A Common Stock have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of Class A Common Stock will not be supervised by, the Swiss Financial Market Supervisory Authority, or FINMA, and the offer of Class A Common Stock has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes, or CISA. The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of Class A Common Stock.

Notice to Prospective Investors in the Dubai International Financial Centre (DIFC)

This document relates to an Exempt Offer in accordance with the Markets Rules 2012 of the Dubai Financial Services Authority (DFSA). This document is intended for distribution only to persons of a type specified in the Markets Rules 2012 of the DFSA. It must not be delivered to, or relied on by, any other person. The DFSA has no responsibility for reviewing or verifying any documents in connection with Exempt Offers. The DFSA has not approved this prospectus nor taken steps to verify the information set forth herein and has no responsibility for this document. The securities to which this document relates may be illiquid and/or subject to restrictions on their resale. Prospective purchasers of the securities offered should conduct their own due diligence on the securities. If you do not understand the contents of this document you should consult an authorized financial advisor.

In relation to its use in the DIFC, this document is strictly private and confidential and is being distributed to a limited number of investors and must not be provided to any person other than the original recipient, and may not be reproduced or used for any other purpose. The interests in the securities may not be offered or sold directly or indirectly to the public in the DIFC.

Notice to Prospective Investors in the United Arab Emirates

The shares of Class A Common Stock have not been, and are not being, publicly offered, sold, promoted or advertised in the United Arab Emirates (including the Dubai International Financial Centre) other than in compliance with the laws of the United Arab Emirates (and the Dubai International Financial Centre) governing the issue, offering and sale of securities. Further, this prospectus does not constitute a public offer of securities in the United Arab Emirates (including the Dubai International Financial Centre) and is not intended to be a public offer. This prospectus has not been approved by or filed with the Central Bank of the United Arab Emirates, the Securities and Commodities Authority or the Dubai Financial Services Authority.

Notice to Prospective Investors in Australia

This prospectus:

- does not constitute a disclosure document or a prospectus under Chapter 6D.2 of the Corporations Act 2001 (Cth) (Corporations Act);
- has not been, and will not be, lodged with the Australian Securities and Investments Commission (ASIC), as a disclosure document for the purposes of the Corporations Act and does not purport to include the information required of a disclosure document for the purposes of the Corporations Act; and

- may only be provided in Australia to select investors who are able to demonstrate that they fall within one or more of the categories of investors, available under section 708 of the Corporations Act, Exempt Investors.

The Class A Common Stock may not be directly or indirectly offered for subscription or purchased or sold, and no invitations to subscribe for or buy the Class A Common Stock may be issued, and no draft or definitive offering memorandum, advertisement or other offering material relating to any shares may be distributed in Australia, except where disclosure to investors is not required under Chapter 6D of the Corporations Act or is otherwise in compliance with all applicable Australian laws and regulations. By submitting an application for the Class A Common Stock, you represent and warrant to us that you are an Exempt Investor.

As any offer of Class A Common Stock under this document will be made without disclosure in Australia under Chapter 6D.2 of the Corporations Act, the offer of those securities for resale in Australia within 12 months may, under section 707 of the Corporations Act, require disclosure to investors under Chapter 6D.2 if none of the exemptions in section 708 applies to that resale. By applying for the Class A Common Stock you undertake to us that you will not, for a period of 12 months from the date of issue of the Class A Common Stock, offer, transfer, assign or otherwise alienate those Class A Common Stock to investors in Australia except in circumstances where disclosure to investors is not required under Chapter 6D.2 of the Corporations Act or where a compliant disclosure document is prepared and lodged with ASIC.

Notice to Prospective Investors in Japan

The shares of Class A Common Stock have not been and will not be registered pursuant to Article 4, Paragraph 1 of the Financial Instruments and Exchange Act. Accordingly, none of the Class A Common Stock nor any interest therein may be offered or sold, 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 a resident of Japan, except pursuant to an exemption from the registration requirements of, and otherwise in compliance with, the Financial Instruments and Exchange Act and any other applicable laws, regulations and ministerial guidelines of Japan in effect at the relevant time.

Notice to Prospective Investors in Hong Kong

The shares of Class A Common Stock have not been offered or sold and will not be offered or sold in Hong Kong, by means of any document, other than (i) to "professional investors" as defined in the Securities and Futures Ordinance (Cap. 571 of the Laws of Hong Kong), or the SFO, of Hong Kong and any rules made thereunder; or (ii) in other circumstances which do not result in the document being a "prospectus" as defined in the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Cap. 32) of Hong Kong), or the CO, or which do not constitute an offer to the public within the meaning of the CO. No advertisement, invitation or document relating to the Class A Common Stock has been or may be issued or has been or may be in the possession of any person for the purposes of issue, 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 to do so under the securities laws of Hong Kong) other than with respect to shares of Class A 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 thereunder.

Notice to Prospective Investors in Singapore

Singapore SFA Product Classification — In connection with Section 309B of the SFA and the CMP Regulations 2018, unless otherwise specified before an offer of shares of Class A Common Stock, we have determined, and hereby notify all relevant persons (as defined in Section 309A(1) of the SFA), that the shares of Class A Common Stock are "prescribed capital markets products" (as defined in the CMP Regulations 2018) and

Excluded Investment Products (as defined in MAS Notice SFA 04-N12: Notice on the Sale of Investment Products and MAS Notice FAA-N16: Notice on Recommendations on Investment Products).

Each underwriter has acknowledged that this prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, each underwriter has represented and agreed that it has not offered or sold any shares of Class A Common Stock or caused the Class A Common Stock to be made the subject of an invitation for subscription or purchase and will not offer or sell any shares of Class A Common Stock or cause the Class A Common Stock to be made the subject of an invitation for subscription or purchase, and has not circulated or distributed, nor will it circulate or distribute, this prospectus or any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the Class A Common Stock, whether directly or indirectly, to any person in Singapore other than:

(i) to an institutional investor (as defined in Section 4A of the Securities and Futures Act (Chapter 289) of Singapore, as modified or amended from time to time, or the SFA) pursuant to Section 274 of the SFA;

(ii) to a relevant person (as defined in Section 275(2) of the SFA) pursuant to Section 275(1) of the SFA 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 Class A Common Stock are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

(i) 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

(ii) 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 or securities-based derivatives contracts (each term as defined in Section 2(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 pursuant to an offer made under Section 275 of the SFA except:

(a) to an institutional investor or to a relevant person, or to any person arising from an offer referred to in Section 276(4)(i)(B) of the SFA,

(b) where no consideration is or will be given for the transfer,

(c) where the transfer is by operation of law,

(d) as specified in Section 276(7) of the SFA, or

(e) as specified in Regulation 37A of the Securities and Futures (Offers of Investments) (Securities and Securities-based Derivatives Contracts) Regulations 2018.

Notice to Prospective Investors in Bermuda

Shares of Class A Common Stock may be offered or sold in Bermuda only in compliance with the provisions of the Investment Business Act of 2003 of Bermuda which regulates the sale of securities in Bermuda. Additionally, non-Bermudian persons (including companies) may not carry on or engage in any trade or business in Bermuda unless such persons are permitted to do so under applicable Bermuda legislation.

Notice to Prospective Investors in Saudi Arabia

This document may not be distributed in the Kingdom of Saudi Arabia except to such persons as are permitted under the Offers of Securities Regulations as issued by the board of the Saudi Arabian Capital Market Authority,

or the CMA, pursuant to resolution number 2-11-2004 dated 4 October 2004 as amended by resolution number 1-28-2008, as amended, or the CMA Regulations. The CMA does not make any representation as to the accuracy or completeness of this document and expressly disclaims any liability whatsoever for any loss arising from, or incurred in reliance upon, any part of this document. Prospective purchasers of the securities offered hereby should conduct their own due diligence on the accuracy of the information relating to the securities. If you do not understand the contents of this document, you should consult an authorized financial adviser.

Notice to Prospective Investors in the British Virgin Islands

The shares of Class A Common Stock are not being, and may not be offered to the public or to any person in the British Virgin Islands for purchase or subscription by or on behalf of us. The Class A Common Stock may be offered to companies incorporated under the BVI Business Companies Act, 2004 (British Virgin Islands), or BVI Companies, but only where the offer will be made to, and received by, the relevant BVI Company entirely outside of the British Virgin Islands.

Notice to Prospective Investors in China

This prospectus will not be circulated or distributed in the PRC and the Class A Common Stock will not be offered or sold, and will not be offered or sold to any person for re-offering or resale directly or indirectly to any residents of the PRC except pursuant to any applicable laws and regulations of the PRC. Neither this prospectus nor any advertisement or other offering material may be distributed or published in the PRC, except under circumstances that will result in compliance with applicable laws and regulations.

Notice to Prospective Investors in Korea

The shares of Class A Common Stock have not been and will not be registered under the Financial Investments Services and Capital Markets Act of Korea, or the FSCMA, and the decrees and regulations thereunder and the shares have been and will be offered in Korea as a private placement under the FSCMA. None of the Class A Common Stock may be offered, sold or delivered directly or indirectly, or offered or sold to any person for re-offering or resale, directly or indirectly, in Korea or to any resident of Korea except pursuant to the applicable laws and regulations of Korea, including the FSCMA and the Foreign Exchange Transaction Law of Korea, or the FETL, and the decrees and regulations thereunder. The Class A Common Stock has not been listed on any of securities exchanges in the world including, without limitation, the Korea Exchange in Korea. Furthermore, the purchaser of the Class A Common Stock shall comply with all applicable regulatory requirements (including but not limited to requirements under the FETL) in connection with the purchase of the Class A Common Stock. By the purchase of the Class A Common Stock, the relevant holder thereof will be deemed to represent and warrant that if it is in Korea or is a resident of Korea, it purchased the Class A Common Stock pursuant to the applicable laws and regulations of Korea.

Notice to Prospective Investors in Taiwan

The Class A Common Stock has not been and will not be registered with the Financial Supervisory Commission of Taiwan pursuant to relevant securities laws and regulations and may not be sold, issued or offered within Taiwan through a public offering or in circumstances which constitutes an offer within the meaning of the Securities and Exchange Act of Taiwan that requires a registration or approval of the Financial Supervisory Commission of Taiwan. No person or entity in Taiwan has been authorized to offer, sell, give advice regarding or otherwise intermediate the offering and sale of the Class A Common Stock in Taiwan.

Notice to Prospective Investors in South Africa

Due to restrictions under the securities laws of South Africa, no “offer to the public” (as such term is defined in the South African Companies Act, No. 71 of 2008 (as amended or re-enacted), or the South African

Companies Act, is being made in connection with the issue of the Class A Common Stock in South Africa. Accordingly, this document does not, nor is it intended to, constitute a "registered prospectus" (as that term is defined in the South African Companies Act) prepared and registered under the South African Companies Act and has not been approved by, and/or filed with, the South African Companies and Intellectual Property Commission or any other regulatory authority in South Africa. The shares of Class A Common Stock are not offered, and the offer shall not be transferred, sold, renounced or delivered, in South Africa or to a person with an address in South Africa, unless one or other of the following exemptions stipulated in section 96 (1) applies:

Section 96 (1)(a)	the offer, transfer, sale, renunciation or delivery is to: (i) persons whose ordinary business, or part of whose ordinary business, is to deal in securities, as principal or agent; (ii) the South African Public Investment Corporation; (iii) persons or entities regulated by the Reserve Bank of South Africa; (iv) authorized financial service providers under South African law; (v) financial institutions recognized as such under South African law; (vi) a wholly-owned subsidiary of any person or entity contemplated in (iii), (iv) or (v), acting as agent in the capacity of an authorized portfolio manager for a pension fund, or as manager for a collective investment scheme (in each case duly registered as such under South African law); or (vii) any combination of the person in (i) to (vi), or
Section 96 (1)(b)	the total contemplated acquisition cost of the securities, for any single addressee acting as principal is equal to or greater than ZAR1,000,000 or such higher amount as may be promulgated by notice in the Government Gazette of South Africa pursuant to section 96(2)(a) of the South African Companies Act.

Information made available in this prospectus should not be considered as "advice" as defined in the South African Financial Advisory and Intermediary.

LEGAL MATTERS

The validity of the shares of our Class A Common Stock being offered in this prospectus will be passed upon for us by Cooley LLP, San Francisco, California. Certain legal matters in connection with this offering will be passed upon for the underwriters by Davis Polk & Wardwell LLP, Menlo Park, California.

EXPERTS

The financial statements of ACELYRIN, INC. as of December 31, 2021 and for the year then ended included in this prospectus have been so included in reliance on the report of PricewaterhouseCoopers LLP, an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

The financial statements of ValenzaBio, Inc. as of December 31, 2021 and for the year then ended included in this prospectus have been so included in reliance on the report of Macias Gini & O'Connell LLP, an independent registered public accounting firm, appearing elsewhere herein, given on the authority of said firm as experts in auditing and accounting.

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 Class A Common Stock offered by this prospectus. This prospectus, which constitutes a part of the registration statement, does not contain all the information set forth in the registration statement, some of which is 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 Class A Common Stock, we refer you to the registration statement, including the exhibits filed as a part of the registration statement. Statements contained in this prospectus concerning the contents of any contract or any other document are not necessarily complete. If a contract or document has been filed as an exhibit to the registration statement, please see the copy of the contract or document that has been filed. 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 also maintains an internet website that contains reports and other information about issuers, like us, that file electronically with the SEC. The address of that website is www.sec.gov.

On the closing of this offering, we will be subject to the information reporting requirements of the Exchange Act, and we will file reports, proxy statements and other information with the SEC. These reports, proxy statements and other information will be available for inspection and copying at the public reference room and website of the SEC referred to above.

We also maintain a website at www.acelyrin.com. Information contained in, or accessible through, our website is not a part of this prospectus, and the inclusion of our website address in this prospectus is only as an inactive textual reference.

INDEX TO FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of ACELYRIN, INC.

Opinion on the Financial Statements

We have audited the accompanying balance sheet of ACELYRIN, INC. (the "Company") as of December 31, 2021, and the related statements of operations and comprehensive loss, of redeemable convertible preferred stock and stockholders' deficit and of cash flows for the year then ended, including 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 as of December 31, 2021, and the results of its operations and its cash flows for the year then ended in conformity with accounting principles generally accepted in the United States of America.

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 audit. 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 audit of these financial statements 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.

Our audit 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 audit 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 audit provides a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP
San Diego, California
February 10, 2023

We have served as the Company's auditor since 2022.

ACELYRIN, INC.
Financial Statements
December 31, 2021

Balance Sheet
(in thousands, except share and per share data)

	December 31, 2021
Assets	
Current assets:	
Cash	$ 102,242
Prepaid expenses and other current assets	62
Total assets	$ 102,304
Liabilities, redeemable convertible preferred stock and stockholders' deficit	
Current liabilities:	
Accounts payable	$ 1,133
Accrued research and development expenses	9,697
Accrued compensation and other current liabilities	910
Total liabilities	11,740
Commitments and contingencies (Note 4)	
Redeemable convertible preferred stock, par value of $0.00001 per share; 56,230,900 shares authorized as of December 31, 2021; 32,115,450 shares issued and outstanding as of December 31, 2021; aggregate liquidation preference $133,000 as of December 31, 2021	132,620
Stockholders' deficit:	
Common stock, par value of $0.00001 per share; 123,230,900 shares authorized as of December 31, 2021; 5,640,000 shares issued and outstanding as of December 31, 2021	—
Additional paid-in capital	250
Accumulated deficit	(42,306)
Total stockholders' deficit	(42,056)
Total liabilities, redeemable convertible preferred stock, and stockholders' deficit	$ 102,304

The accompanying notes are an integral part of these financial statements.

ACELYRIN, INC.
Financial Statements
December 31, 2021

Statement of Operations and Comprehensive Loss
(in thousands, except share and per share data)

	Year Ended December 31, 2021
Operating expenses:	
Research and development	$ 38,230
General and administrative	3,564
Total operating expenses	41,794
Loss from operations	(41,794)
Other income (expense), net	(45)
Net loss and comprehensive loss	$ (41,839)
Net loss per share attributable to common stockholders, basic and diluted	$ (30.86)
Weighted-average common shares outstanding, basic and diluted	1,355,553

The accompanying notes are an integral part of these financial statements.

ACELYRIN, INC.
Financial Statements
December 31, 2021

Statement of Redeemable Convertible Preferred Stock and Stockholders' Deficit
(in thousands, except share data)

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount			
Balance at January 1, 2021	8,000,000	$ 7,916	5,600,000	$ —	$ 1	$ (467)	$ (466)
Issuance of Series B redeemable convertible preferred stock for cash, net of issuance costs of $296	24,115,450	124,704	—	—	—	—	—
Common shares issued upon exercise of options	—	—	40,000	—	16	—	16
Stock-based compensation expense	—	—	—	—	233	—	233
Net loss	—	—	—	—	—	(41,839)	(41,839)
Balance at December 31, 2021	32,115,450	$ 132,620	5,640,000	$ —	$ 250	$ (42,306)	$ (42,056)

The accompanying notes are an integral part of these financial statements.

ACELYRIN, INC.
Financial Statements
December 31, 2021

Statement of Cash Flows
(in thousands)

	Year Ended December 31, 2021
Cash flows from operating activities	
Net loss	$ (41,839)
Adjustments to reconcile net loss to net cash used in operations:	
Stock-based compensation expense	233
Expense related to acquired in-process research and development assets	25,000
Changes in assets and liabilities:	
Prepaid expenses and other current assets	(49)
Accounts payable	1,119
Accrued research and development expenses	9,697
Accrued compensation and other current liabilities	860
Net cash used in operating activities	(4,979)
Cash flows from investing activities	
Cash paid to acquire in-process research and development assets	(25,000)
Net cash used in investing activities	(25,000)
Cash flows from financing activities	
Proceeds from issuance of redeemable convertible preferred stock, net of issuance costs	124,704
Proceeds from issuance of common stock related to exercised stock options	16
Net cash provided by financing activities	124,720
Net increase in cash	94,741
Cash, at beginning of year	7,501
Cash, at end of year	$ 102,242

The accompanying notes are an integral part of these financial statements.

ACELYRIN, INC.
Financial Statements
December 31, 2021

Notes to the Financial Statements

1. Description of Business, Organization and Liquidity

Organization and Business

ACELYRIN, INC. (the "Company") is a late-stage biopharma company focused on identifying, acquiring, and accelerating the development and commercialization of transformative medicines. The Company was incorporated in the State of Delaware on July 27, 2020. Since its inception, the Company has devoted substantially all of its resources to organizing the Company, hiring personnel, business planning, acquiring and developing its product candidates, performing research and development, enabling manufacturing activities in support of its product development efforts, establishing and protecting its intellectual property portfolio, raising capital, and providing general and administrative support for these activities.

The Company did not have any significant operations from the inception date until August 2021. On August 9, 2021, the Company entered into the License and Collaboration Agreement with Affibody AB, a Swedish company, and licensed worldwide development, manufacturing and commercialization rights to a therapeutic candidate, izokibep, for use in the treatment of inflammatory and autoimmune disorders, excluding rights in certain Asian and Nordic countries. See Note 3 for further details.

Liquidity

The Company has incurred significant losses and negative cash flows from operations since its inception. During the year ended December 31, 2021, the Company incurred a net loss of $41.8 million. As of December 31, 2021, the Company had an accumulated deficit of $42.3 million.

The Company has historically financed its operations primarily through the sale of shares of its redeemable convertible preferred stock in private placements. As of December 31, 2021, the Company had cash of $102.2 million. The Company does not have any products approved for sale and has not generated any revenue from product sales. The Company expects to continue to incur significant and increasing expenses and substantial losses for the foreseeable future as it continues its development of and seeks regulatory approvals for its product candidates and commercializes any approved products, seeks to expand its product pipeline and invests in its organization. The Company's ability to achieve and sustain profitability will depend on its ability to successfully develop, obtain regulatory approval for and commercialize its product candidates. There can be no assurance that the Company will ever earn revenue or achieve profitability, or if achieved, that the revenue or profitability will be sustained on a continuing basis. Unless and until it does, the Company will need to continue to raise additional capital. The Company has a commitment from its Series C investors to purchase an additional $150.0 million of shares of Series C redeemable convertible preferred stock on June 30, 2023 ("the Series C Second Tranche Closing") if an initial public offering is not completed by such date. Management expects that existing cash together with the Series C Second Tranche Closing of $150.0 million (Note 11) will be sufficient to fund its current operating plan for at least the next 12 months from the date of issuance of these financial statements. The commitment for the Series C Second Tranche includes certain conditions. If those conditions are not met, the Series C Second Tranche Closing will be terminated and the Company will have to decrease expenditures on current and future development programs. While the Company has been able to raise multiple rounds of financing, there can be no assurance that additional financing will be available on terms which are favorable or at all. Failure to generate sufficient cash flows from operations, raise additional capital or reduce certain discretionary spending would have a material adverse effect on the Company's ability to achieve its intended business objectives.

Impact of the COVID-19 Pandemic

The current COVID-19 pandemic, which is impacting worldwide economic activity, poses risk that the Company or its employees, contractors, suppliers, and other partners may be prevented from conducting business activities for an indefinite period of time, including due to shutdowns that may be requested or mandated by governmental authorities. Although the impact of COVID-19 has not been material to the Company and its operations, the extent to which the COVID-19 pandemic will impact the Company's business will depend on future developments that are highly uncertain and cannot be predicted at this time.

2. Summary of Significant Accounting Policies

Basis of Presentation

These financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP").

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of expenses during the reporting period. On an ongoing basis, the Company evaluates estimates and assumptions, including but not limited to those related to the fair value of its common stock, stock-based compensation expense, accruals for research and development expenses, valuation of deferred tax assets, and uncertain income tax positions. Management bases its estimates on historical experience and on various other assumptions 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 materially from those estimates.

Segment Information

The Company has one operating segment. The Company's focus is the research, development and commercialization of product candidates. The Company's chief executive officer, who is the chief operating decision maker, reviews financial information on an aggregate basis for allocating and evaluating financial performance. All long-lived assets are maintained in the United States of America.

Cash

As of December 31, 2021, the Company's cash was deposited in a checking account.

Fair Value of Financial Instruments

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The carrying amounts of financial instruments, prepaid expenses and other current assets, accounts payable, accrued expenses, and other liabilities, approximate fair value due to their short-term maturities.

Carrying amounts of the Company's financial instruments, including cash and accounts payable, approximate fair value due to their relatively short maturities and market interest rates, if applicable.

The Company discloses and recognizes the fair value of its assets and liabilities using a hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to valuations based upon unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to valuations based upon unobservable inputs that are significant to the valuation (Level 3 measurements). The guidance establishes three levels of the fair value hierarchy as follows:

Level 1—Observable inputs, such as quoted prices in active markets for identical assets or liabilities.

Level 2—Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

Assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires management to make judgments and considers factors specific to the asset or liability.

Concentration of Credit Risk

Cash is a financial instrument that potentially subjects the Company to concentrations of credit risk. All of the Company's cash is deposited in accounts at one financial institution, and account balances may at times exceed federally insured limits.

Risks and Uncertainties

The Company is subject to certain risks and uncertainties, including, but not limited to, changes in any of the following areas that the Company believes could have a material adverse effect on the future financial position or results of operations: the timing of, and the Company's ability to advance its current and future product candidates into and through clinical development; costs and timelines associated with the manufacture of clinical supplies of the Company's product candidates; regulatory approval and market acceptance of, and reimbursement for its product candidates; performance of third-party vendors; competition from companies with greater financial resources or expertise; protection of the intellectual property; litigation or claims against the Company based on intellectual property or other factors; compliance with government regulations; and its ability to attract and retain employees necessary to support its growth.

The Company has expended and will continue to expend substantial funds to complete the research, development and clinical testing of its product candidates. The Company also will be required to expend additional funds to establish commercial-scale manufacturing arrangements and to provide for the marketing and distribution of products that receive regulatory approval. If any of its product candidates are approved, the Company will require additional funds to commercialize its products. The Company is unable to entirely fund these efforts with its current financial resources. If adequate funds are unavailable on a timely basis from additional sources of financing, the Company may have to delay, reduce the scope of or eliminate one or more of its research or development programs, which would materially and adversely affect its business, financial condition and operations.

Patent Costs

All patent-related costs incurred in connection with filing and prosecuting patent applications are expensed as incurred due to the uncertainty of the recovery of the expenditure. Amounts incurred are classified as general and administrative expenses in the statements of operations and comprehensive loss.

Asset Acquisitions and Acquired In-Process Research and Development Expenses

The Company measures and recognizes asset acquisitions that are not deemed to be business combinations based on the cost to acquire the asset or group of assets, which includes transaction costs. Goodwill is not recognized in asset acquisitions. In an asset acquisition, the cost allocated to acquire in-process research and development ("IPR&D") with no alternative future use is recognized as expense on the acquisition date.

Contingent consideration in asset acquisitions payable in the form of cash is recognized in the period the triggering event is determined to be probable of occurrence and the related amount is reasonably estimable. Such amounts are expensed or capitalized based on the nature of the associated asset at the date the related contingency is resolved.

Deferred Issuance Costs

The Company capitalizes certain legal, accounting and other third-party fees that are directly associated with in-process equity financings as deferred offering costs until such financings are consummated. After consummation of the equity financing, these costs are recorded as a reduction of the proceeds from the offering, either as a reduction of the carrying value of preferred stock or in stockholders' deficit as a reduction of additional paid-in capital generated as a result of the offering. Should the in-process equity financing be abandoned, the deferred offering costs would be expensed immediately as a charge to operating expenses in the statement of operations and comprehensive loss. The Company had no deferred offering costs recorded as of December 31, 2021.

Redeemable Convertible Preferred Stock

The Company records shares of redeemable convertible preferred stock at their respective fair values on the dates of issuance, net of issuance costs. The redeemable convertible preferred stock is recorded outside of permanent equity because while it is not mandatory, redemption is contingent upon the occurrence of certain events considered not solely within the Company's control. The Company has not adjusted the carrying values of the redeemable convertible preferred stock to the liquidation preferences of such shares because a deemed liquidation event obligating the Company to pay the liquidation preferences to holders of shares of redeemable convertible preferred stock is not probable of occurring. Subsequent adjustments to the carrying values to the liquidation preferences will be made only when it becomes probable that such a deemed liquidation event will occur.

Research and Development Expenses and Accrued Liabilities

Research and development costs are expensed as incurred. Research and development costs include salaries, stock-based compensation, and benefits for employees performing research and development activities, expenses incurred under agreements with consultants, third parties' organizations and vendors that conduct clinical studies, other supplies and costs associated with product development efforts, preclinical activities, and regulatory operations. Payments associated with licensing agreements to acquire exclusive licenses to develop, use, manufacture and commercialize products that have not reached technological feasibility and do not have alternate future use are also expensed as incurred.

Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are capitalized and recorded in prepaid expenses and other current assets, and then expensed as the related goods are delivered or the services are performed.

The Company records accrued liabilities for estimated costs of its research and development activities conducted by third-party service providers. The Company accrues for these costs based on factors such as estimates of the work completed and in accordance with the third-party service agreements. If the Company does not identify costs that has begun to be incurred or if the Company underestimate or overestimate the level of services performed or the costs of these services, actual expenses could differ from the estimates. To date, the Company has not experienced any material differences between accrued costs and actual costs incurred.

The Company makes payments in connection with clinical trials to contract manufacturing organizations ("CMOs") that manufacture the material for its product candidates and to clinical research organizations ("CROs") and clinical trial sites that conduct and manage the Company's clinical trials. The financial terms of these contracts are subject to negotiation, which vary by contract and may result in payments that do not match the periods over which materials or services are provided. 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. In the event the Company makes advance payments for goods or services that will be used or rendered for future research and development activities, the payments are deferred and capitalized as a prepaid expense and recognized as expense as the goods are received or the related services are rendered. These payments are evaluated for current or long-term classification based on when they are expected to be realized.

Stock-Based Compensation Expense

The Company grants stock options to employees, consultants and members of its board of directors (the "Board"). These awards are accounted at fair value on the award grant date. Stock-based compensation expense is recognized over the awards' vesting period on a straight-line basis and recorded as either research and development or general and administrative expenses in the statements of operations and comprehensive loss based on the function to which the related services are provided. Forfeitures are accounted for as they occur.

The Company uses the Black-Scholes option pricing model to determine the fair value of stock options. The use of the Black-Scholes option pricing model requires the Company to make assumptions with respect to the fair value of the Company's common stock at grant date, expected term of the option, the expected volatility of the common stock consistent with the expected life of the option, risk-free interest rates and expected dividend yields of the common stock.

Stock-based compensation expense related to stock options granted to non-employees is recognized based on the fair value of the stock options, determined using the Black-Scholes option pricing model. The awards generally vest over the time period the Company expects to receive service from the non-employee.

Foreign Currency Transactions

Transactions denominated in foreign currencies are initially measured in U.S. dollars using the exchange rate on the date of the transaction. Foreign currency denominated monetary assets and liabilities are subsequently remeasured at the end of each reporting period using the exchange rate at that date, with the corresponding foreign currency transaction gain or loss recorded in the statements of operations and comprehensive loss.

Income Taxes

The Company accounts for income taxes using the asset and liability method. The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns. Deferred tax assets and liabilities are determined based on the difference 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.

In evaluating the ability to recover deferred income tax assets, the Company considers all available positive and negative evidence, including operating results, ongoing tax planning and forecasts of future taxable income on a jurisdiction-by-jurisdiction basis. In the event the Company determines that it would be able to realize deferred income tax assets in the future in excess of their net recorded amount, the Company would make an adjustment to the valuation allowance that would reduce the provision for income taxes. Conversely, in the event that all or part of the net deferred tax assets are determined not to be realizable in the future, an adjustment to the valuation allowance would be charged to earnings in the period when such determination is made. As of December 31, 2021, the Company had recorded a full valuation allowance on deferred tax assets.

Tax benefits related to uncertain tax positions are recognized when it is more likely than not that a tax position will be sustained during an audit. The tax benefit recognized is measured as the largest amount of benefit which is more likely than not to be realized upon settlement with the taxing authority. Changes in recognition or measurement are reflected in the period in which the change in judgement occurs. Interest and penalties related to unrecognized tax benefits are included within the provision for income tax.

Net Loss Per Share Attributable to Common Stockholders

Basic net loss per common share is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding during the period, without consideration of potentially dilutive securities. Diluted net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common stock and potentially dilutive securities outstanding for the period. For purposes of the diluted net loss per share calculation, the redeemable convertible preferred stock, common stock subject to repurchase, and stock options are considered to be potentially dilutive securities.

Basic and diluted net loss attributable to common stockholders per share is presented in conformity with the two-class method required for participating securities as the redeemable convertible preferred stock and common stock subject to repurchase are considered participating securities The Company's participating securities do not have a contractual obligation to share in the Company's losses. As such, the net loss is attributed entirely to common stockholders. Because the Company has reported a net loss for the reporting periods presented, the diluted net loss per common share is the same as basic net loss per common share for those periods.

Comprehensive Loss

Comprehensive loss includes net loss as well as other changes in stockholders' deficit that result from transactions and economic events other than those with stockholders. There were no components of other comprehensive loss for the periods presented. Thus, comprehensive loss equals net loss for all periods presented.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board (the "FASB") or other standard setting bodies and adopted by the Company as of the specified effective date. The Company qualifies as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, as amended (the "JOBS Act"), and has elected not to "opt out" of the extended transition related to complying with new or revised accounting standards, which means that when a standard is issued or revised and it has different application dates for public and nonpublic companies, the Company will adopt the new or revised standard at the time nonpublic companies adopt the new or revised standard and will do so until such time that the Company either (i) irrevocably elects to "opt out" of such extended transition period or (ii) no longer qualifies as an emerging growth company. The Company may choose to early adopt any new or revised accounting standards whenever such early adoption is permitted for nonpublic companies.

Recently Adopted Accounting Pronouncements

On January 1, 2021, the Company adopted Accounting Standards Update ("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 simplifies the accounting for convertible instruments by reducing the number of accounting models available for convertible debt instruments. This guidance also eliminates the treasury stock method to calculate diluted earnings per share for convertible instruments and requires the use of the if-converted method. The adoption did not have a material impact on the Company's financial statements and related disclosures.

Recent Accounting Pronouncements Not Yet Adopted

In June 2016, the FASB issued ASU 2016-13, *Credit Losses*. The FASB also issued amendments and the initial ASU, and all updates are included herein as the Credit Losses standard or Topic 326. The new standard generally applies to financial assets and requires those assets to be reported at the amount expected to be realized. The ASU will become effective for fiscal years beginning after December 15, 2022, and interim periods within those fiscal years. The Company is currently assessing the potential impact of adopting ASU 2016-13 on its financial statements and related disclosures.

3. Significant Agreements

Affibody License and Collaboration Agreement

On August 9, 2021, the Company entered into a license agreement with Affibody AB ("Affibody") (the "Affibody Agreement") under which Affibody granted the Company exclusive, sublicensable licenses to develop, commercialize and manufacture products containing izokibep for all human therapeutic uses on a worldwide basis, subject to a pre-existing agreement with Inmagene Biopharmaceuticals (Inmagene) with respect to certain Asian countries.

The Company chairs a global joint steering committee composed of designees from Affibody, Inmagene and the Company and retains final decision-making authority for izokibep global development. In doing so, the Company is obligated to use commercially reasonable efforts (i) to develop products containing izokibep worldwide, excluding certain defined territories, (ii) for the conduct and finalization of certain ongoing clinical trials, and (iii) to commercialize products containing izokibep for all human therapeutic uses worldwide, excluding certain defined territories, after obtaining the applicable marketing authorization. The Company is responsible for manufacturing both the clinical and commercial supply of licensed product globally.

In connection with the Affibody Agreement, the Company paid a non-refundable upfront license fee in the aggregate amount of $3.0 million in August 2021 and September 2021, and $22.0 million in October 2021. The Company is also obligated to pay Affibody (i) an aggregate of up to $280.0 million, $30.0 million of which would be due prior to the first approval in the United States, upon the achievement of various development, regulatory and commercialization milestones and (ii) high single-digit to low-teens royalties on net sales of licensed products in the territory where the Company has commercialization rights, subject to certain reductions. Royalties will be due on a licensed product-by-licensed product and country-by-country basis beginning after the first commercial sale of the licensed product, except in Mainland China, Hong Kong, Macau, Taiwan and South Korea, and lasting until the later of (a) the expiration of all valid patent claims or regulatory exclusivity covering the licensed product in that country and (b) ten years after such first commercial sale.

In the event the FDA grants the Company (or its affiliates or sublicensees) a priority review voucher for a licensed product, the Company will pay Affibody either: (a) if the Company sells or transfer such priority review voucher to a third-party, approximately one third of the proceeds received from the sale, net of taxes, or (b) if the Company uses the priority review voucher for an indication or product outside the scope of the Affibody Agreement, approximately one third of the fair market value of the priority review voucher as determined in accordance with the Affibody Agreement.

Unless earlier terminated, the Affibody Agreement will continue on a licensed product-by-licensed product basis and country-by-country basis until there are no more royalty payments owed to Affibody on any licensed product thereunder.

The acquisition of the exclusive license was accounted for as an in-process research and development asset acquisition and as the acquired technology did not have an alternative use, the total consideration of $25.0 million was recorded as research and development expense in the statement of operations and comprehensive loss for the year ended December 31, 2021. Milestone payments are contingent consideration and are accrued when contingent events occur and achievement of milestones is probable. Royalties will be recognized as cost of sales when products are sold and royalties are payable. No milestone or royalties were probable and estimable as of December 31, 2021.

4. Commitments and Contingent Liabilities

License Agreements

The Company entered into the Affibody License Agreement in 2021 (Note 3), pursuant to which the Company is required to pay certain milestones contingent upon the achievement of specific development and regulatory events. No such milestones were achieved or probable as of December 31, 2021. The Company is required to pay royalties on sales of products developed under these agreements. Izokibep was in clinical trials as of December 31, 2021 and no such royalties were due.

Legal Contingencies

From time to time, the Company may become involved in legal proceedings arising from the ordinary course of business. The Company records a liability for such matters when it is probable that future losses will be incurred and that such losses can be reasonably estimated. Significant judgment by the Company is required to determine both probability and the estimated amount. Management is not aware of any legal matters that could have a material adverse effect on the financial position, results of operations or cash flows.

Guarantees and Indemnifications

In the normal course of business, the Company enters into agreements that contain a variety of representations and provide for general indemnification. Its exposure under these agreements is unknown because it involves claims that may be made against the Company in the future. To the extent permitted under Delaware law, the Company has agreed to indemnify its directors and officers for certain events or occurrences while the director or officer is, or was serving, at a request in such capacity. To date, the Company has not paid any claims or been required to defend any action related to its indemnification obligations. As of December 31, 2021, the Company did not have any material indemnification claims that were probable or reasonably possible and consequently has not recorded related liabilities.

5. Redeemable Convertible Preferred Stock

In October 2020, the Company issued 8,000,000 shares of its Series A redeemable convertible preferred stock (the "Series A Stock") at a price of $1.00 per share for aggregate gross cash proceeds of $8.0 million, and incurred issuance costs of $0.1 million.

In October 2021, the Company entered into Series B stock purchase agreement and issued 24,115,450 shares of its Series B redeemable convertible preferred stock (the "Series B Stock") at a price of $5.1834 per share for aggregate gross cash proceeds of $125.0 million, and incurred issuance costs of $0.3 million. The Company also agreed to issue and the investors also agreed to purchase additional 24,115,450 shares of the Series B Stock at the same price per share within 15 days of the earliest to occur: (i) January 30, 2022; (ii) the Company filing a Form S-1 with the Securities and Exchange Commission; or (iii) a date determined by the majority of the Board when the Company has a critical need for additional capital (the "Series B Second Tranche"). The Company closed the Series B Second Tranche and received $125.0 million in aggregate gross proceeds in February 2022. The obligation to issue and purchase shares was concluded to be a tranche right liability. The fair value of the liability was estimated to be *de minimis* at the issuance date and at the closing date, as the expected term was three months, and there were no significant changes in the estimated fair value of the Series B Stock at the Series B Second Tranche closing date.

Redeemable convertible preferred stock as of December 31, 2021, consisted of the following (in thousands, except share data):

	December 31, 2021			
	Shares Authorized	Shares Issued and Outstanding	Aggregate Liquidation Preference	Net Carrying Value
Series A redeemable convertible preferred stock	8,000,000	8,000,000	$ 8,000	$ 7,916
Series B redeemable convertible preferred stock	48,230,900	24,115,450	125,000	124,704
Total redeemable convertible preferred stock	56,230,900	32,115,450	$ 133,000	$ 132,620

The significant rights, preferences and privileges of the Company's redeemable convertible preferred stock are as follows:

Dividends—The holders of Series A Stock and Series B Stock are entitled to receive noncumulative dividends at the rate of 8% of the original issue price per share, when, as and if declared by the Board. No dividends were declared and payable for the year ended December 31, 2021.

Liquidation Rights—In the event of the liquidation, dissolution, or winding up of the Company, or a deemed liquidation event, including a merger or consolidation, or a sale or other disposition of all or substantially all of the Company's assets, the holders of shares of Series B Stock are entitled to receive, before any payments are made to the holders of Series A Stock or common stock, an amount per share equal to the greater of: (i) the Series B Stock original issuance price of $5.1834, plus any dividends declared but unpaid; or (ii) such amount per share as would have been payable had all shares of B Stock been converted into common stock immediately prior to such liquidation, dissolution, winding up or deemed liquidation. Should the Company's legally available assets be insufficient to satisfy the Series B liquidation preference, the funds will be distributed with equal priority and pro rata among the holders of the Series B Stock in proportion to the preferential amount each holder is otherwise entitled to receive.

After full payment to holders of the Series B Stock, a payment would be made to the holders of Series A Stock, in preference to the holders of the common stock, in an amount per share equal to the greater of: (i) the Series A Stock original issuance price of $1.00, plus any dividends declared but unpaid; or (ii) such amount per share as would have been payable had all shares of Series A Stock been converted into common stock immediately prior to such liquidation, dissolution, winding up or deemed liquidation. Should the Company's legally available assets be insufficient to satisfy the Series A Stock liquidation preference, the funds will be distributed with equal priority and pro rata among the holders of the Series A Stock in proportion to the preferential amount each holder is otherwise entitled to receive.

After the payment to the holders of Series A Stock and Series B Stock of the full preferential amounts, the entire remaining assets of the Company legally available for distribution shall be distributed with equal priority and pro rata among the holders of the common stock in proportion to the number of shares of common stock held by them.

Conversion—Each share of Series A Stock and Series B Stock is convertible at the option of a holder at any time into a number of shares of the Company's common stock at a conversion rate, which is the Series A Stock and Series B Stock original issuance price, $1.00 and $5.1834, respectively, divided by the Series A Stock and Series B Stock conversion price in effect at the time of conversion. If, after the issuance date of the Series A Stock and Series B Stock, the Company issues or sells, or is deemed to have sold, additional shares of common stock at a price lower than the original issuance price of the Series A Stock or Series B Stock, except for certain exceptions allowed the conversion price of the Series A Stock and/or the Series B Stock would be adjusted. The Series A Stock and Series B Stock conversion prices are initially equal to the Series A Stock and Series B Stock original issue prices, and are subject to recapitalization and other adjustments, as provided in the Company's certificate of incorporation. As of December 31, 2021, the conversion rates are one-for-one.

All outstanding shares of Series A Stock and Series B Stock are automatically converted into shares of the Company's common stock, at the then effective Series A Stock and Series B Stock conversion price upon earlier of: (i) the closing of the sale of shares of common stock to the public, in a firm-commitment underwritten public offering pursuant to an effective registration statement under the Securities Act of 1933, as amended (the

"Securities Act"), resulting in at least $75.0 million of gross proceeds to the Company approved by the Board, including the approval of at least one Series A Director and at least one Series B director (an "IPO"); or (ii) upon a vote or a written consent for such conversion from the holders of a majority of the outstanding shares of Series A Stock and Series B Stock voting together on an as-converted to common stock basis.

A holder of Series B Stock that owns directly or indirectly more than 9.9% of the Company's outstanding shares (excluding Class B Common Stock) immediately following an IPO, a non-IPO registration of a SPAC transaction or a deemed liquidation event, shall have the right to elect to receive shares of capital stock of the Company that would be issued upon conversion of this investor's shares held in excess of 9.9% in the form of Class B non-voting common stock.

Voting Rights—The holders of redeemable convertible preferred stock and the holders of common stock vote together and not as separate classes. Each holder of Series A Stock and Series B Stock is entitled to the number of votes equal to the number of shares of common stock into which the shares of Series A Stock and Series B Stock could be converted as of the record date.

For as long shares of redeemable convertible preferred stock remain outstanding, Series A stockholders and Series B stockholders, voting as a separate class, are entitled to elect four members of the Board and have certain protective provisions, as defined in the certificate of incorporation. The remaining members of the Board are elected by the holders of redeemable convertible preferred stock and common stock, voting together as a single class on an as-converted basis.

Redemption—The redeemable convertible preferred stock is recorded in mezzanine equity because while it is not mandatorily redeemable, it will become redeemable at the option of the preferred stockholders upon the occurrence of certain deemed liquidation events that are considered not solely within the Company's control.

6. Common Stock

As of December 31, 2021, the Company was authorized to issue 75,000,000 and 48,230,900 shares of its Class A common stock and Class B common stock with $0.00001 par value per share, respectively. Under the Company's amended and restated certificate of incorporation filed on October 19, 2021, each share of the Company's common stock issued and outstanding prior to this date, was reclassified and became one share of Class A common stock.

The rights, preferences and privileges of the holders of the Company's Class A common stock and Class B common stock are subject to and qualified by the rights, preferences and privileges of the holders of the Company's redeemable convertible preferred stock. Each share of the Company's Class A common stock is entitled to one vote. Holders of Class B common stock shall not be entitled to vote on any matter on which the holders of Class A common stock or Series A Stock or Series B Stock shall be entitled to vote, and shares of Class B common stock shall not be included in determining the number of shares of common stock voting or entitled to vote on any such matters. Shares of Class B common stock are convertible into Class A common stock upon written notice of the holder, subject to a maximum of 9.9% total beneficial ownership in Class A common stock upon such conversion.

The holders of common stock are also entitled to receive dividends whenever funds are legally available and when declared by the Board, subject to prior rights of holders of redeemable convertible preferred stock outstanding. Dividend rights for Class A and Class B common stock are the same. As of December 31, 2021, no

dividends had been declared to date. As of December 31, 2021, there were no shares of Class B common stock outstanding.

As of December 31, 2021, the Company reserved Class A common stock for future issuance was as follows:

	December 31, 2021
Redeemable convertible preferred stock	56,230,900
Outstanding stock options	950,500
Shares available for future grants under Equity Inceptive Plan	9,525,037
Total shares reserved for future issuance	66,706,437

Founders' Common Stock

In July 2020, the Company issued 5,600,000 shares of its Class A common stock to founders at a price of $0.00001 per share. The issuance price was the estimated fair value of the shares as shares were issued at inception and no intellectual property was contributed by the founders. The founders have voting rights and rights to receive dividends regardless of the vesting of the shares. Issued shares vest monthly over 48 months, as founders continue providing services to the Company. The Company has a right to repurchase unvested shares at the price paid by the founders if services are terminated. As of December 31, 2021, 3,500,000 shares were unvested and 1,500,000 founders shares vested during the year ended December 31, 2021. No shares were cancelled or repurchased during the year ended December 31, 2021 and for the period from the Company's inception date to December 31, 2020. Stock-based compensation expense was minimal for these shares.

7. Equity Incentive Plan

The Company grants stock-based awards under the 2020 Stock Option Plan, as amended on October 19, 2021 (the "2020 Plan"). The Company may grant incentive stock options, nonstatutory stock options and restricted stock awards to the Company's officers, employees, directors and consultants. Options granted under the Plan may be either incentive stock options (''ISOs''), non-qualified stock options (''NSOs''), restricted stock awards ("RSAs"), unrestricted stock awards ("USAs") or restricted stock units ("RSUs"). ISOs may be granted only to employees. At December 31, 2021, 10,515,537 shares of the Company's common stock were reserved for issuance under the 2020 Plan.

Options under the 2020 Plan may be granted for periods of up to 10 years. Options generally vest monthly over four years with or without one-year cliff vesting.

The table below presents a summary of activities and a reconciliation of common shares authorized and remaining for grant under the 2020 Plan:

	December 31, 2021
Shares authorized under 2020 Plan	10,515,537
Options granted	(1,110,500)
Forfeited	120,000
Remaining shares available for grant as of December 31	9,525,037

Stock Options

Stock options issued under the 2020 Plan, generally, vest over a four-year period and expire ten years from the date of grant. Certain options provide for accelerated vesting if there is a change in control, as defined in the individual award agreements.

A summary of option activity under the 2020 Plan is as follows:

	Number of Options	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of January 1, 2021	160,000	$ 0.39	9.94	$ 45
Granted	950,500	$ 0.39		
Exercised	(40,000)	$ 0.39		$ 64
Forfeited and expired	(120,000)	$ 0.39		
Outstanding as of December 31, 2021	950,500	$ 0.39	9.60	$ 1,578
Exercisable as of December 31, 2021	13,333	$ 0.39	9.56	$ 22
Vested and expected to vest as of December 31, 2021	950,500	$ 0.39	9.60	$ 1,578

Aggregate intrinsic value represents the difference between the fair value of the underlying common stock and the exercise price as of December 31, 2021. The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying stock options and the estimated fair value of the Company's common stock for those stock options that had exercise prices lower than the estimated fair value of the Company's common stock at December 31, 2021. Fair value of shares vested during 2021 totaled less than $0.1 million. The weighted-average grant date fair value of options granted in 2021 was $1.51. For the year ended December 31, 2021, the intrinsic value and cash received for the stock options exercised were $64,000 and $16,000, respectively. No options were exercised for the period from the Company's inception date to December 31, 2020.

The terms of the 2020 Plan permit the exercise of options prior to vesting, subject to required approvals. The shares are subject to the Company's lapsing repurchase right upon termination of employment at an amount equal to the lower of: (i) the original purchase price and (ii) the fair market value at the time the Company's right of repurchase is exercised. The Company's right to repurchase these shares lapses as those shares vest over the requisite service period. Shares purchased pursuant to the early exercise of stock options are not deemed, for accounting purposes, to be issued until those shares vest according to their respective vesting schedules. Cash received for early exercised stock options is recorded as accrued liabilities and other current liabilities on the balance sheet and is reclassified to additional paid-in capital as such shares vest. Shares issued upon the early exercise of options are included in outstanding common stock shares and participate in voting and dividends rights. There were no early exercises of options during the year ended December 31, 2021.

Stock-Based Compensation Expense

The Black-Scholes option pricing model, used to estimate fair value of stock-based awards, requires the use of the following assumptions:

- *Fair value of common stock*. The fair market value of the Company's common stock is determined by the Board with assistance from management and external valuation experts. The approach to estimating the fair market value of common stock is consistent with the methods outlined in the American Institute of Certified Public Accountants' Accounting and Valuation Guide*, Valuation of Privately-Held Company Equity Securities Issued as Compensation (*the "Practice Aid").

  For valuations performed prior to December 31, 2021, the Company utilized an Option Pricing Method ("OPM") based analysis, primarily the OPM backsolve methodology, to determine the estimated fair value of the common stock. Within the OPM framework, the backsolve method for inferring the total equity value implied by a recent financing transaction involves the construction of an allocation model that takes into account our capital structure and the rights, preferences and privileges of each class of stock, then assumes reasonable inputs for the other OPM variables (expected time to liquidity, volatility, and risk-free rate). The total equity value is then iterated in the model until the model output value for the equity class sold in a recent financing round equals the price paid in that round. The OPM is generally utilized when specific future liquidity events are difficult to forecast (i.e., the enterprise has many choices and options available), and the enterprise's value depends on how well it follows an uncharted path through the various possible opportunities and challenges. In determining the estimated fair value of the common stock, the Board also considered the fact that the stockholders could not freely trade the common stock in the public markets. Accordingly, the Company applied discounts to reflect the lack of marketability of its common stock based on the weighted-average expected time to liquidity. The estimated fair value of the common stock at each grant date reflected a non-marketability discount partially based on the anticipated likelihood and timing of a future liquidity event.

  The Company also considers the amount of time between the independent third-party valuation dates and the grant date of an award. The Company interpolates the common stock fair value between the two valuation dates, if there are any significant internal or external events occurred during this period. The incremental stock-based compensation expense recorded as a result of the retrospective review was insignificant.

- *Expected term*. The expected term represents the period that the stock-based awards are expected to be outstanding. The expected term for the Company's stock options was calculated based on the weighted-average vesting term of the awards and the contract period, or simplified method.

- *Expected volatility*. Since the Company is not yet a public company and does not have any trading history for its common stock, the expected volatility was estimated based on the average historical volatilities of common stock of comparable publicly traded entities over a period equal to the expected term of the stock option grants. The comparable companies were chosen based on their size, stage of their life cycle or area of specialty. The Company will continue to apply this process until enough historical information regarding the volatility of its stock price becomes available.

- *Risk-free interest rate*. The risk-free interest rate is based on the U.S. Treasury yield in effect at the time of grant for zero-coupon U.S. Treasury notes with maturities approximately equal to the expected term of the awards.

- *Expected dividend yield*. The Company has never paid dividends on the common stock and has no plans to pay dividends on the common stock. Therefore, the Company used an expected dividend yield of zero.

The Company used the following assumptions for the year ended December 31, 2021:

	Year Ended December 31, 2021
Fair value of common stock	$1.61- $1.81
Expected term (in years)	5.93 - 6.06
Expected volatility	99.97% - 100.78%
Expected dividend yield	0%
Risk-free interest rate	0.87% - 0.97%

The following table presents the classification of stock-based compensation expense related to awards granted to employees and non-employees (in thousands):

	Year Ended December 31, 2021
Research and development expenses	$ 214
General and administrative expenses	19
Total stock-based compensation expense	$ 233

As of December 31, 2021, there was $1.3 million of unrecognized stock-based compensation expense related to the employee and non-employee awards, which is expected to be recognized over a weighted-average period of 3.46 years.

8. Related Party Transactions

In the year ended December 31, 2021, the Company paid $7,869 to one of the stockholders as a reimbursement of consulting and due diligence fees.

9. Net Loss Per Share Attributable to Common Stockholders

The following table sets forth the computation of basic and diluted net loss per share attributable to common stockholders (in thousands, except share and per share data):

	Year Ended December 31, 2021
Numerator:	
Net loss	$ (41,839)
Denominator:	
Weighted-average common shares outstanding	5,607,014
Less: Weighted-average common shares subject to repurchase	(4,251,461)
Weighted-average common shares outstanding, basic and diluted	1,355,553
Net loss per share attributable to common stockholders, basic and diluted	$ (30.86)

The following outstanding shares of potentially dilutive securities were excluded from the computation of diluted net loss per share attributable to common stockholders for the periods presented because including them would have been antidilutive:

	As of December 31, 2021
Redeemable convertible preferred stock	32,115,450
Common stock subject to repurchase	3,500,000
Outstanding options to purchase common stock	950,500
Total	36,565,950

10. Income Taxes

No provision for income taxes was recorded for the year ended December 31, 2021 as the Company operated with taxable losses. The Company has incurred net operating losses only in the United States since its inception.

A reconciliation of the U.S. federal statutory income tax rate to the Company's effective income tax rate was as follows:

	Year Ended December 31, 2021
Income tax computed at federal statutory rate	21.00%
State taxes	0.26
Other permanent differences	(0.11)
Research credits	0.19
Change in valuation allowance	(21.34)
Effective income tax rate	—%

Significant components of the deferred tax assets for federal and state income taxes were as follows (in thousands):

	Year Ended December 31, 2021
Deferred Tax Assets:	
Net operating loss carry forwards	$ 3,561
Intangibles	5,133
Research credits	136
Other	197
Total deferred tax assets	9,027
Less: Valuation allowance	(9,027)
Net deferred tax assets	$ —

A valuation allowance is required to be established when it is more likely than not that all or a portion of a deferred tax asset will not be realized. Realization of deferred tax assets is dependent upon future earnings, the timing and amount of which are uncertain. The Company believes that, based on a number of factors such as the history of operating losses, it is more likely than not that the deferred tax assets will not be fully realized, such that a full valuation allowance has been recorded. The valuation allowance increased by $8.9 million for the year ended December 31, 2021 primarily due to the net operating losses carryforwards and research and development credits.

The following table sets forth the Company's federal and state net operating loss carryforwards as of December 31, 2021 (dollars in thousands):

	Amount	Begin to Expire
Net operating losses, Federal	$ 16,855	Do not expire
Net operating losses, California	$ 641	2041

The Company's U.S. federal net operating loss carryforwards of $16.9 million, which may be available to offset future taxable income, are limited in their usage to an annual deduction equal to 80% of annual taxable income.

The Company had research credit carryforwards of $0.1 million for federal and state income tax purposes as of December 31, 2021. The federal credits begin to expire in 2041 and the state credits can be carried forward indefinitely.

Utilization of some of the federal and state net operating loss and credit carryforwards may be subject to annual limitations due to the change in ownership provisions of the Internal Revenue Code of 1986, as amended ("Internal Revenue Code"), and similar state provisions. The annual limitation may result in the expiration of net operating losses and credits before utilization. The Company has not performed a study under Section 382 of the Internal Revenue Code to determine if a change in control did occur and, as such, is not able to determine the impact on the net operating loss carryforwards, if any, as of the date of the financial statements.

Uncertain Tax Positions

A reconciliation of the beginning and ending balances of the unrecognized tax benefits during the year ended December 31, 2021 is as follows (in thousands):

	Year Ended December 31, 2021
Beginning balance	$ —
Increase in tax positions in the current period	48
Ending balance	$ 48

Uncertain tax positions prior to the year ended December 31, 2021, were minimal. As of December 31, 2021, uncertain tax positions of $48,000, if recognized, would not affect the Company's effective tax rate. The Company recognizes interest accrued related to unrecognized tax benefits and penalties as income tax expense. Related to the unrecognized tax benefits noted above, the Company did not accrue any penalties or interest during tax year 2021 due to available tax losses.

The Company is subject to examination by the U.S. federal and state tax authorities for the tax years 2020 and later. State income tax returns are generally subject to examination for a period of four years after filing of the respective return. To the extent the Company has tax attribute carryforwards, the tax years in which the attribute was generated may still be adjusted upon examination by the Internal Revenue Service and state tax authorities to the extent utilized in a future period.

11. Subsequent Events

The Company has reviewed and evaluated subsequent events as of December 31, 2021 through February 10, 2023, the date that the financial statements were available to be issued.

Series B Second Tranche Financing

In February 2022, the Company closed the Series B Second Tranche financing and issued 24,115,450 shares of its Series B Stock with aggregate gross proceeds of $125.0 million (Note 5).

Series C Stock Purchase Agreement

In September 2022, the Company entered into a Series C stock purchase agreement and issued 24,115,368 shares of its Series C redeemable convertible preferred stock at a price of $6.2201 per share for aggregate gross cash proceeds of $150.0 million in the Series C First Tranche Closing, and incurred issuance costs of $0.2 million. The Company also agreed to issue and investors agreed to purchase additional 24,115,368 shares of the Company's Series C redeemable convertible preferred stock at the same purchase price of $6.2201 per share on June 30, 2023 in the Series C Second Tranche Closing, under certain conditions. The obligation of each investor to purchase shares at the Series C Second Tranche Closing are subject to the fulfillment, on or before such closing, of each of the following conditions: (i) there has not occurred a closing of a deemed liquidation event, as defined in the Company's certificate of incorporation; (ii) there has not occurred a closing of the Company's first underwritten public offering of its Class A Common Stock under the Securities Act or a direct listing; (iii) the Company has not filed for bankruptcy; (iv) the Company's existing chief executive officer is employed full time; (v) a majority of the Board including at least one independent director has not resolved to (a) discontinue the development of izokibep or (b) remove the Phase 3 development of axial spondyloarthritis from the Company's long-range plan; and (vi) a majority of the Board's independent directors has not determined that a material adverse change, as defined in the Series C stock purchase agreement, has occurred since the Series C First Tranche Closing. If on June 30, 2023, any of the conditions specified above have not been met, the Series C Second Tranche Closing will be terminated. The rights, preferences and privileges of the Series C stockholders are similar as Series B stockholders, except that in the event of the liquidation, dissolution, or winding up of the Company, or a deemed liquidation event, they are entitled to their liquidation preference amount before any distribution to Series B stockholders. The obligation of the Series C investors to purchase shares was concluded to be a tranche right liability and upon the Series C First Tranche Closing in September 2022, the Company recorded a preferred stock tranche right liability of $10.8 million and a corresponding reduction to the carrying value of the Series C redeemable preferred stock.

Acquisition of ValenzaBio

On December 20, 2022, the Company entered into the ValenzaBio Merger Agreement to acquire outstanding equity of ValenzaBio. The acquisition closed on January 4, 2023. ValenzaBio was a privately held company developing therapies for autoimmune and inflammatory diseases. As consideration, at the closing, the Company (i) issued 37,242,709 shares of its Class A common stock to ValenzaBio stockholders and paid $16,050 in cash to one non-accredited investor and (ii) assumed options of ValenzaBio optionholders who

entered into consulting agreements with the Company, which are now exercisable for an aggregate of 2,464,653 shares of the Company's Class A common stock. Outstanding shares and options were exchanged at an exchange ratio of 1.582963-for-one. The assumed options vest in full on the earliest of (i) March 31, 2023, or (ii) the termination of the optionholder's consulting agreement without cause. Each assumed option is exercisable until the earlier of (i) 12 months following the termination of the optionholder's continuous service with the Company, or (ii) the original expiration date of such assumed option.

On December 20, 2022, in connection with the acquisition of ValenzaBio, the Company became the successor to and negotiated an amendment to a pre-existing license and commercialization agreement between ValenzaBio and Pierre Fabre Medicament SAS ("Pierre Fabre") (the "Pierre Fabre Agreement"). In connection with the Pierre Fabre Agreement, the Company received certain exclusive worldwide licenses with the right to sublicense to certain patents, know-how and other intellectual property to develop, manufacture, use and commercialize lonigutamab for non-oncology therapeutic indications. In connection with the amendment to the Pierre Fabre Agreement, the Company paid Pierre Fabre an additional license payment of $10.0 million. In connection with the acquisition of ValenzaBio, the Company issued Pierre Fabre 1,668,326 shares of the Company's Class A common stock in exchange for 1,053,319 shares of ValenzaBio's Series A preferred stock. The Company is obligated to (i) make payments of up to $99.5 million upon the achievement of various development and regulatory milestones, (ii) make milestone payments of up to $390.0 million upon the achievement of certain commercial milestones and (iii) pay tiered royalties in the high single-digit to low-teens percentages to Pierre Fabre on worldwide net sales in a given calendar year.

On January 4, 2023, in connection with the acquisition of ValenzaBio, the Company became the successor to an exclusive license agreement between ValenzaBio and Novelty Nobility (the "Novelty License Agreement") and obtained a worldwide exclusive license for the development and commercialization of XLRN-517, an unmodified IgG1 monoclonal antibody, as a therapeutic treatment. Under the terms of the assumed Novelty License Agreement, the Company has exclusive rights to develop and commercialize products containing XLRN-517. In connection with the arrangement, the Company is obligated to (i) make development and regulatory milestones of up to $44.3 million, (ii) make commercial sales milestone payments of up to $682.0 million and (iii) pay tiered royalties of a low single-digit to high-single-digit percentage on future worldwide net sales.

Lease Agreement

On January 6, 2023, the Company entered into an agreement to lease 10,012 square feet of office space located in Agoura Hills, California. The term of the lease is 65 months with an option to extend the term by additional three-year period. Monthly rent payments are approximately $30,500, subject to an annual 3.0% increase and six months rental abatement during the first year. The Company's total rent commitments under the lease agreement are $1.9 million throughout the lease term. In addition to base rent, the Company pays its share of operating expenses and taxes.

INDEPENDENT AUDITOR'S REPORT

To the Stockholders and Board of Directors of ValenzaBio, Inc.

Opinion

We have audited the financial statements of ValenzaBio, Inc. (the "Company"), which comprise the balance sheet as of December 31, 2021, the related statements of operations and comprehensive loss, convertible preferred stock and stockholders' deficit, and cash flows for the year then ended, and the related notes to the financial statements (collectively, the "financial statements").

In our opinion, the accompanying financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2021, and the results of its operations and its cash flows for the year then ended in accordance with accounting principles generally accepted in the United States of America.

Basis for Opinion

We conducted our audit in accordance with auditing standards generally accepted in the United States of America (GAAS). Our responsibilities under those standards are further described in the Auditor's Responsibilities for the Audit of the Financial Statements section of our report. We are required to be independent of the Company and to meet our other ethical responsibilities, in accordance with the relevant ethical requirements relating to our audits. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

Other Matter

In our report dated April 29, 2022, we expressed an unmodified opinion on the 2021 financial statements of the Company. As described in Note 2, the Company has revised its presentation of the convertible preferred stock and common stock in the financial statements for the year ended December 31, 2021.

Responsibilities of Management for the Financial Statements

Management is responsible for the preparation and fair presentation of the financial statements in accordance with accounting principles generally accepted in the United States of America, and for the design, implementation, and maintenance of internal control relevant to the preparation and fair presentation of financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the financial statements, management is required to evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern for one year after the date that the financial statements are issued.

Auditor's Responsibilities for the Audit of the Financial Statements

Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our

opinion. Reasonable assurance is a high level of assurance but is not absolute assurance and therefore is not a guarantee that an audit conducted in accordance with GAAS will always detect a material misstatement when it exists. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control. Misstatements are considered material if there is a substantial likelihood that, individually or in the aggregate, they would influence the judgment made by a reasonable user based on the financial statements.

In performing an audit in accordance with GAAS, we:

- Exercise professional judgment and maintain professional skepticism throughout the audit.
- Identify and assess the risks of material misstatement of the financial statements, whether due to fraud or error, and design and perform audit procedures responsive to those risks. Such procedures include examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements.
- Obtain an understanding of internal control relevant to the audit 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 Company's internal control. Accordingly, no such opinion is expressed.
- Evaluate the appropriateness of accounting policies used and the reasonableness of significant accounting estimates made by management, as well as evaluate the overall presentation of the financial statements.
- Conclude whether, in our judgment, there are conditions or events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern for a reasonable period of time.

We are required to communicate with those charged with governance regarding, among other matters, the planned scope and timing of the audit, significant audit findings, and certain internal control–related matters that we identified during the audit.

San Jose, California
April 29, 2022, except for Note 2 as to
which the date is February 10, 2023

VALENZABIO, INC.
Balance Sheet
As of December 31, 2021
(*Amounts expressed in thousands, except shares*)

	December 31, 2021
ASSETS	
Current assets:	
Cash and cash equivalents	$ 9,865
Investments at fair value, current	21,972
Prepaid expenses and other current assets	2,612
Total current assets	34,449
Investments at fair value	22,484
Total assets	$ 56,933
LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT	
Current liabilities:	
Accounts payable	$ 3,381
Accrued expenses and other current liabilities	4,898
Total liabilities	8,279
Commitments and Contingencies	
Series Seed convertible preferred stock, $0.0001 par value; 7,453,129 shares authorized, issued and outstanding at December 31, 2021, liquidation preference of $14,834	14,834
Series A convertible preferred stock, $0.0001 par value; 8,918,106 shares authorized, issued and outstanding at December 31, 2021, liquidation preference of $79,375	79,115
Stockholders' Deficit:	
Common stock, $0.0001 par value; 26,838,582 shares authorized; 7,444,684 issued and outstanding at December 31, 2021	—
Additional paid-in capital	759
Accumulated deficit	(45,915)
Accumulated comprehensive loss	(139)
Total stockholders' deficit	(45,295)
Total liabilities, convertible preferred stock and stockholders' deficit	$ 56,933

VALENZABIO, INC.
Statement of Operations and Comprehensive Loss
For the Year Ended December 31, 2021
(*Amounts expressed in thousands, except shares*)

	Year Ended December 31, 2021
Operating expenses:	
Research and development	$ 35,233
General and administrative	2,737
Total operating expenses	37,970
Loss from operations	(37,970)
Other income:	
Interest income	70
Net loss	$ (37,900)
Other comprehensive loss:	
Unrealized loss on investments	(139)
Total comprehensive loss	$ (38,039)

VALENZABIO, INC.
Statement of Convertible Preferred Stock and Stockholders' Deficit
For the Year Ended December 31, 2021
(*Amounts expressed in thousands, except shares*)

	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Other Comprehensive Loss	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount				
Balance at January 1, 2021	7,453,129	$14,834	7,506,015	$ —	$ 114	$ (8,015)	$ —	$ (7,901)
Other comprehensive loss	—	—	—	—	—	—	(139)	(139)
Issuance of common stock upon exercise of stock options	—	—	14,327	—	5	—	—	5
Forfeiture of unvested restricted shares	—	—	(75,658)	—	—	—	—	—
Issuance of Series A convertible preferred stock for cash, net of issuance costs	7,864,787	69,740	—	—	—	—	—	—
Issuance of Series A convertible preferred stock as a payment for Pierre Fabre license fee	1,053,319	9,375	—	—		—	—	—
Stock-based compensation	—	—	—	—	640	—	—	640
Net loss	—	—	—	—	—	(37,900)	—	(37,900)
Balance at December 31, 2021	16,371,235	$93,949	7,444,684	$ —	$ 759	$ (45,915)	$ (139)	$ (45,295)

VALENZABIO, INC.
Statement of Cash Flows
For the Year Ended December 31, 2021
(*Amounts expressed in thousands, except shares*)

	Year Ended December 31, 2021
Cash flows from operating activities	
Net loss	$ (37,900)
Adjustments to reconcile net loss to net cash used in operations:	
Stock-based compensation expense	640
Amortization of premium on marketable securities	584
Preferred shares issued as payment for license agreement	9,375
Changes in assets and liabilities:	
Prepaid expenses and other current assets	(2,604)
Accounts payable	2,891
Accrued expenses and other current liabilities	3,780
Net cash used in operating activities	(23,234)
Cash flows from investing activities	
Purchase of investments	(57,227)
Proceeds from maturities of investments	12,048
Net cash used in investing activities	(45,179)
Cash flows from financing activities	
Proceeds from issuance of convertible preferred stock	69,740
Proceeds from exercise of stock options	5
Net cash provided by financing activities	69,745
Net increase in cash and cash equivalents	1,332
Cash, and cash equivalents at beginning of year	8,533
Cash, and cash equivalents at end of year	$ 9,865

VALENZABIO, INC.
Notes to Financial Statements
For the Year Ended December 31, 2021
(*Amounts expressed in thousands, except shares*)

1. Nature of the Business

ValenzaBio, Inc. (the "Company") is a biopharmaceutical company focused on the identification, acquisition, and development of therapies for serious orphan autoimmune and inflammatory diseases. The Company is developing a pipeline of differentiated monoclonal antibodies with clinically validated mechanisms of action targeting diseases where the biology for treatment is clear but the approved therapies are few and suboptimal. The Company was incorporated on December 6, 2019, in Delaware. The Company is devoting substantially all of its efforts towards product research and development.

Liquidity

The Company has incurred significant losses from its inception. During the year ended December 31, 2021, the Company incurred a net loss of $37.9 million. As of December 31, 2021, the Company had an accumulated deficit of $45.9 million. The Company expects to continue to generate operating losses and negative cash flows for the foreseeable future.

The Company has funded its operations primarily through the sale of equity securities. Additional funding will be needed to finance future clinical, preclinical, manufacturing and commercial activities. There is no assurance the Company will be successful in obtaining such additional financing on terms acceptable to it, if at all, and it may not be able to enter into other arrangements. If the Company is unable to obtain funding, it could be forced to delay, reduce or eliminate our research and development programs, portfolio expansion or commercialization efforts, which could adversely affect its business prospects and ability to continue operations.

The Company is subject to risks common to companies in the biopharmaceutical industry. There can be no assurance that the Company's research and development will be successfully completed, that adequate protection for its intellectual property will be maintained, that any products developed will obtain required regulatory approval, or that any approved products will be commercially viable. Even if the development efforts are successful, it is uncertain when, if ever, the Company will generate significant product sales and ultimately net income.

Coronavirus Pandemic

In March 2020, the World Health Organization declared the COVID-19 outbreak a pandemic. The worldwide COVID-19 pandemic has affected and may affect in the future the Company's ability to initiate and complete preclinical studies, delay the initiation and completion of its current and planned clinical trials, disrupt regulatory activities or have other adverse effects on its business, results of operations, financial condition and prospects. In addition, the pandemic has caused substantial disruption in the financial markets and may adversely impact economies worldwide, both of which could adversely affect the Company's business, operations and ability to raise funds to support its operations.

The Company cannot be certain what the overall impact of the COVID-19 pandemic will be on its business, and it has the potential to adversely affect its business, financial condition, results of operations and prospects.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America ("US GAAP").

2. Summary of Significant Accounting Policies (Continued)

Presentation of the Convertible Preferred Stock and Common Stock

Convertible preferred stock is presented in the financial statements at their respective fair values on the dates of issuance, net of issuance costs. The convertible preferred stock is recorded outside of permanent equity because while it is not mandatory, redemption is contingent upon the occurrence of certain events considered not solely within the Company's control. The Company has not adjusted the carrying values of the redeemable convertible preferred stock to the liquidation preferences of such shares because it is uncertain whether or when a deemed liquidation event would occur that would obligate the Company to pay the liquidation preferences to holders of shares of redeemable convertible preferred stock. Subsequent adjustments to the carrying values to the liquidation preferences will be made only when it becomes probable that such a deemed liquidation event will occur.

Common stock issued and outstanding include the following: (1) 5,187,500 founders' shares, of which 2,555,922 shares have the Company's right of repurchase as of December 31, 2021; and (2) 2,242,857 issued restricted stock awards, of which 1,207,938 shares have the Company's right of repurchase as of December 31, 2021. As these are legally issued and outstanding shares and have voting and dividends rights, these are fully included in the statement of convertible preferred stock and stockholders' deficit.

Use of Estimates

The preparation of financial statements in conformity US GAAP requires management to make estimates, judgements and assumptions that may affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. These estimates are based on information available as of the date of the financial statements; therefore, actual results could differ from those estimates.

Stock-Based Compensation—Employee Stock-Based Awards

The Company applies the provisions of Accounting Standards Codification ("ASC") 718, *Compensation— Stock Compensation*, which requires measurement and recognition of compensation expense for all stock-based awards made to employees, directors, and consultants based on estimated fair values and recognizes stock-based compensation expense of those awards over the requisite service period, which is generally the vesting period of the respective award. Generally, the Company issues stock option awards with only service-based vesting conditions and records the expense for these awards using the straight-line method. The Company's policy is to account for forfeitures when they occur by reversing compensation costs when the award is forfeited.

The Company utilizes the Black-Scholes option pricing model for determining the estimated fair value for stock-based awards. The Black-Scholes model requires the use of assumptions which determine the fair value of the stock-based awards. Determining the fair value of stock-based awards at the grant date requires significant judgment, including estimating the expected term of stock options, the expected volatility of the Company's stock and expected dividends.

The Company does not have a history of market prices of its common stock and, as such, volatility is estimated using historical volatilities of similar public companies. The expected term of the employee awards is estimated based on the simplified method, which calculates the expected term based upon the midpoint of the term of the award and the vesting period. The Company uses the simplified method because it does not have

2. Summary of Significant Accounting Policies (Continued)

sufficient option exercise data to provide a reasonable basis upon which to estimate the expected term. The expected dividend yield is 0% as the Company has no history of paying dividends nor does management expect to pay dividends over the contractual terms of these options. The risk-free interest rates are based on the United States Treasury yield curve in effect at the time of grant, with maturities approximating the expected term of the stock options.

The Company classifies stock-based compensation expense in its statement of operations and comprehensive loss in the same manner in which the award recipient's payroll costs are classified or in which the award recipients' service payments are classified.

Accrued Expenses and Other Current Liabilities

As part of the process of preparing financial statements, the Company is required to estimate accrued expenses. This process involves identifying services which have been performed on its behalf and estimating the level of service performed and the associated cost incurred for such service as of each balance sheet date in its financial statements.

In accruing service fees, the Company estimates the time period over which services will be provided and the level of effort in each period. If the actual timing of the provision of services or the level of effort varies from the estimate, the Company will adjust the accrual accordingly. The majority of service providers invoice the Company monthly in arrears for services performed. Some service providers require upfront or milestone payments. If the estimate of services performed is less than the upfront or milestone payments, the difference is accounted for as a prepaid expense. In the event that the Company does not identify costs that have begun to be incurred or the Company underestimates or overestimates the level of services performed or the costs of such services, actual expenses could differ from such estimates. The date on which some services commence, the level of services performed on or before a given date and the cost of such services are often subjective determinations. The Company makes judgments based upon facts and circumstances known to it in accordance with US GAAP.

Cash and Cash Equivalents

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. Cash and cash equivalents held at financial institutions may at times exceed federally insured amounts. The Company believes it mitigates such risk by investing in or through major financial institutions.

Fair Value of Financial Instruments

The Company applies the provisions of ASC 820, *Fair Value Measurements and Disclosures,* for financial assets and liabilities measured on a recurring basis which requires disclosure that establishes a framework for measuring fair value. The guidance requires that fair value measurements be classified and disclosed in one of three categories:

Level 1: Quoted prices in active markets for identical assets and liabilities that the reporting entity has the ability to access at the measurement date;

Level 2: Inputs other than quoted prices in active markets, that are observable either directly or indirectly, such as quoted prices for similar assets or liabilities, quoted in markets that are not active, or other inputs that are observable; or

2. Summary of Significant Accounting Policies (Continued)

Level 3: Unobservable inputs.

The fair value of the Company's investments as of December 31, 2021, was valued based on Level 2 inputs. The Company's investments consist mainly of corporate debt securities. Fair value is determined by taking into consideration valuations obtained from third-party pricing services. The third-party pricing services utilize industry standard valuation models, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. These inputs include reported trades of and broker/dealer quotes on the same or similar securities; issuer credit spreads; benchmark securities; and other observable inputs.

The Company has assessed these as Level 2 within the fair value hierarchy of ASC 820. The Company classifies its entire investment portfolio as available for sale as defined in ASC 320, *Debt and Equity Securities*. Securities are carried at fair value with the unrealized gains (losses) reported as a separate component of convertible preferred stock and stockholders' deficit within accumulated other comprehensive loss. Realized gains and losses on available for sale securities are included in net loss in the period earned or incurred.

The carrying amount of cash, cash equivalents, other receivables, and accounts payable approximates their fair value due to the short-term maturity of these instruments.

Concentration of Risk

Concentration of credit risk exists with respect to cash and cash equivalents and investments. The Company maintains its cash and cash equivalents and investments with high quality financial institutions. At times, amounts may exceed federally insured deposit limits.

Research and Development Expenses

All costs associated with internal research and development, research and development services for which the Company has externally contracted and licensed are expensed as incurred. Research and development expense includes direct and indirect costs for salaries, employee benefits, subcontractors, including clinical research organizations ("CROs"), license and milestone fees and operating supplies.

The Company records accrued expenses for estimated costs incurred for research and development activities conducted by third-party service providers based upon the estimated amount of services performed. The Company estimates the amount of work completed through discussions with internal personnel and external service providers as to the progress or stage of completion of the services and the agreed-upon fee to be paid for such services. The Company records advance payments made to service providers as prepaid assets, which are expensed over the contract term based on the estimate of services performed.

Patent Costs

The Company expenses the costs of obtaining and maintaining patents as general and administrative expense.

Comprehensive Loss

Comprehensive loss represents net loss for the period plus the results of certain other changes in the stockholders' deficit. The Company's comprehensive loss included unrealized losses related to investments for the year ended December 31, 2021.

2. Summary of Significant Accounting Policies (Continued)

Income Taxes

The Company uses the asset and liability approach for financial accounting and reporting of income taxes. Deferred tax assets and liabilities are determined based on temporary differences between financial reporting and tax basis of assets and liabilities and are measured by applying enacted rates and laws to taxable years in which differences are expected to be recovered or settled. Further, the effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that the rate change is enacted. A valuation allowance is required when it is "more likely than not" that all or a portion of deferred tax assets will not be realized.

The Company applies the provisions of ASC 740, *Income Taxes*, which prescribes a comprehensive model for how a company should recognize, measure, present, and disclose in its financial statements uncertain tax positions that the company has taken or expects to take on a tax return (including a decision whether to file or not file a return in a particular jurisdiction). The financial statements reflect expected future tax consequences of such positions presuming the taxing authorities' full knowledge of the position and all relevant facts.

In December 2019, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2019-12, *Simplifying the Accounting for Income Taxes,* which simplifies the accounting for income taxes, eliminates certain exceptions within ASC 740, *Income Taxes*, and clarifies certain aspects of the current guidance to promote consistency among reporting entities. ASU 2019-12 is effective for fiscal years beginning after December 15, 2020. Most amendments within the standard are required to be applied on a prospective basis, while certain amendments must be applied on a retrospective or modified retrospective basis. The adoption of this guidance did not have a material impact on the Company's financial statements and accompanying disclosures.

The Company recognizes a valuation allowance against its net deferred tax assets unless it is more likely than not that such deferred tax assets will be realized. This assessment requires judgement as to the likelihood and amounts of future taxable income by tax jurisdiction. The Company reviews all tax positions to ensure the tax treatment selected is sustainable based on its technical merits and that the position would be sustained if challenged.

Recently Issued Accounting Pronouncements

In February 2016, the FASB issued ASU No. 2016-02, *Leases* (Topic 842), and subsequently has issued additional guidance (collectively, "ASC 842"), which requires companies to generally recognize operating and financing lease liabilities and corresponding right-of-use assets on the balance sheet. ASC 842 will be effective for the Company on January 1, 2022, with early adoption permitted. The Company does not believe the adoption of ASC 842 will have a material impact on the Company's financial statements.

Segment Information

Operating segments are defined as components of an entity for which separate financial information is made available and is regularly evaluated by the chief operating decision maker ("CODM") in making decisions regarding resource allocation and assessing performance. The Company's CODM is its chief executive officer and operations are managed as a single segment for the purposes of assessing performance and making operating decisions.

3. License Agreements

Pierre Fabre License and Commercialization Agreement

In March 2021, the Company entered into a license and commercialization agreement (the "Pierre Fabre License Agreement") with Pierre Fabre Medicament SAS ("Pierre Fabre") relating to the Company's non-oncology therapeutic initiatives. Under the Pierre Fabre License Agreement, the Company was granted a worldwide exclusive license (the "Pierre Fabre License") to research, develop, manufacture, use and commercialize therapeutic products. In consideration for the Pierre Fabre License, the Company paid Pierre Fabre an upfront license fee of $7.5 million and also entered into a Stock Purchase Agreement (the "SPA") with Pierre Fabre in contemplation of the license agreement. Pursuant to the SPA, the Company issued to Pierre Fabre 1,053,319 shares of the Company's Series A Preferred Stock. The upfront cash payment of $7.5 million and the fair value of the preferred stock issued of $9.4 million, totaling $16.9 million, was recognized as research and development expense during the year ended December 31, 2021, as the acquired in-process research and development was determined to have no alternative future use at the time of the acquisition.

In addition, the Company is obligated to pay tiered royalties ranging from low- to high-teen percentages based on net sales of products licensed under the agreement. If the Company receives revenue from sublicensing any of its right under the agreement, the Company is also obligated to pay a portion of that revenue, ranging from mid-single to mid-double-digit percentages to Pierre Fabre. The Company is also obligated to make milestone payments aggregating up to $82.8 million for the first two indications for each licensed product upon the achievement of certain clinical or regulatory milestones and up to $195.0 million in sales-based milestones upon the achievement of certain sales-based events.

The Company has the right to terminate the Pierre Fabre License Agreement for any reason upon a 90-day notice, or if Pierre Fabre becomes insolvent. Pierre Fabre has the right to terminate the agreement if the Company fails to achieve any near-term milestones timely or participates in any action challenging the validity of Pierre Fabre's patents. Both parties have the right to terminate the agreement if the other party materially breaches the agreement and fails to remedy any such default within the specified cure periods. The Pierre Fabre License Agreement will remain in effect until terminated by the parties according to their rights.

ProBioGen Development, Manufacturing Services and License Agreement

In February 2021, the Company entered into a cell line development, manufacturing services and license agreement (the "ProBioGen Agreement") with ProBioGen AG ("ProBioGen") to research, develop and commercialize innovative therapies using ProBioGen's proprietary technology. Upon signing the ProBioGen Agreement, the Company made an upfront payment of $0.6 million as consideration for the license. In addition, the Company is obligated to make milestone payments aggregating up to €18.3 million upon the achievement of certain clinical or regulatory and sales-based milestones. If the Company chooses to contract ProBioGen to perform manufacturing services, the milestone payments will be reduced by €0.9 million. In addition, if the Company receives revenue from sublicensing any of its rights under the agreement, the Company is obligated to pay a portion of that revenue to ProBioGen.

Under the ProBioGen Agreement, the Company also contracted ProBioGen to perform certain research and development services. In July 2021, August 2021 and December 2021, the ProBioGen Agreement was amended to include additional contracted services to be provided by ProBioGen.

Both parties have the right to terminate the agreement if the other party becomes insolvent, or materially breaches the agreement and fails to remedy any such default within the specified cure periods. The ProBioGen

3. License Agreements (Continued)

Agreement, as amended, will remain in effect until the services are completed for the service-related component and until the payment obligations expire in connection with the ProBioGen License component, unless terminated by the parties according to their rights.

During the year ended December 31, 2021, the Company recognized $2.2 million in research and development expense in connection with the ProBioGen Agreement of which $1.0 million related to milestone payments and $1.2 million related to contracted research and development services provided by ProBioGen.

Cancer Technology Research License Agreement

In February 2020, the Company entered into a license agreement (the "CRT License Agreement") with Cancer Research Technology Limited ("CRT") under which the Company was granted a non-exclusive license to research, develop, commercialize and manufacture up to three non-oncology and one oncology drug candidates using certain intellectual property that CRT owns or controls. The Company paid an upfront license fee of $0.4 million to CRT and is also required to pay annual license maintenance fees of £50,000 over the term of the agreement. In addition, the Company is obligated to pay tiered royalties ranging in single-digit percentage based on net sales of products licensed under the agreement. If the Company receives revenue from sublicensing any of its right under the agreement, the Company is obligated to pay a portion of that revenue, ranging from mid-single to teen percentage to CRT. The Company is also obligated to make milestone payments aggregating up to £67.3 million for the first three indications upon the achievement of certain clinical or regulatory milestones and up to £40.0 million in sales-based milestones upon the achievement of certain sales-based events.

Both parties have the right to terminate the agreement if the other party becomes insolvent, or materially breaches the agreement and fails to remedy any such default within the specified cure periods. CRT has the right to terminate the agreement if the Company fails to operate and perform research and development activities as intended in the development plan, seeks to challenge the validity of the licensed patent, becomes insolvent or undergoes a change of control event where the new controlling party is prohibited by CRT. The CRT License Agreement will remain in effect until terminated by the parties according to their rights. In the event there is a termination due to a material breach by the Company, CRT has the right to exercise an assignment option under which the Company will grant CRT rights to certain product-specific intellectual property controlled or owned by the Company that exists as of the date of the termination and allows CRT to develop and commercialize the licensed product worldwide under those rights. CRT is obligated to pay the Company a share of net revenue for any licensed products that have generated sale revenue under the assignment option.

During the year ended December 31, 2021, the Company recognized $0.9 million in research and development expense in connection with the CRT license agreement.

4. Investments

The fair value of the Company's investments of $44,456 as of December 31, 2021 is valued based on Level 2 inputs. The Company's investments consist mainly of corporate debt securities. Fair value is determined by taking into consideration valuations obtained from third-party pricing services. The third-party pricing services utilize industry standard valuation models, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. These inputs include reported trades of and broker/dealer quotes on the same or similar securities; issuer credit spreads; benchmark securities; and other observable inputs. There were no

(Amounts expressed in thousands, except shares)

4. Investments (Continued)

transfers between levels within the hierarchy during the year ended December 31, 2021. The Company has assessed these as Level 2 within the fair value hierarchy of ASC 820. The Company classifies its entire investment portfolio available for sale as defined in ASC 320, *Debt and Equity Securities*. Securities are carried at fair value with the unrealized gains (losses) reported in other comprehensive income.

The unrealized loss from investments was $139 at December 31, 2021.

As of December 31, 2021, none of the Company's investments were determined to be other than temporarily impaired. The following table summarizes the Company's investments:

	December 31, 2021			
	Amortized Cost	Unrealized Gain	Unrealized (Loss)	Estimated Fair Value
Corporate Debt Securities	$ 44,595	$ —	(139)	$ 44,456
Total	$ 44,595	$ —	(139)	$ 44,456

The following table summarizes the contractual maturities of the Company's investments:

	December 31, 2021
Mature in less than one year	$ 21,972
Mature in one to five years	22,484
Total	$ 44,456

5. Prepaid Expenses and Other Current Assets

A summary of prepaid expenses and other current assets is as follows:

	December 31, 2021
Prepaid research and development costs	$ 649
Interest receivable	325
Other receivable	1,565
Other prepaid expenses	73
Total	$ 2,612

(Amounts expressed in thousands, except shares)

6. Accrued Expenses and Other Current Liabilities

Accrued expenses consist of the following:

	December 31, 2021
Accrued compensation	$ 862
Accrued research and development expenses	3,935
Accrued professional expenses	61
Other current liabilities	40
Total	$ 4,898

Accrued research and development expenses are comprised of amounts owed to third-party CROs, clinical investigators, laboratories and data managers for research and development work performed on behalf of the Company.

7. Convertible Preferred Stock and Stockholders' Deficit

Common Stock

At December 31, 2021, the Company had 26,838,582 authorized shares common stock of which 7,444,684 shares were issued and outstanding.

Convertible Preferred Stock

At December 31, 2021, the Company had 7,453,129 shares of Series Seed convertible preferred stock authorized, issued and outstanding ("Series Seed Preferred Stock") and 8,918,106 shares of Series A convertible preferred stock authorized, issued and outstanding ("Series A Preferred Stock").

In March 2021, the Company issued a total of 8,918,106 shares of Series A Preferred Stock. The Company received gross proceeds of $70.0 million. The total Series A Preferred Stock shares issued included 7,864,787 shares issued at a purchase price of $8.90 per share and 1,053,319 shares of Series A Preferred Stock issued to Pierre Fabre Medicament SAS for consideration of a one-time non-refundable license fee in connection with a license and commercialization agreement. The fair value attributable to the shares issued to Pierre Fabre was $9.4 million (see Note 3).

In February and May 2020, the Company issued a total of 7,453,129 shares of Series Seed Preferred Stock at a purchase price of $1.99 per share. The Company received gross proceeds of $14.8 million.

Rights, Preferences and Privileges of Preferred Stock: The rights, preferences and privileges of the Series Seed Preferred Stock and the Series A Preferred Stock (collectively, "Preferred Stock") are as follows:

Voting Rights: On any matter presented to stockholders of the Company for consideration, each holder of outstanding shares of Preferred Stock will be entitled to cast the number of votes equal to the whole number of shares of common stock into which the Preferred Stock held by such holder is convertible into. Holders of Preferred Stock will vote together with the holders of common stock as a single class on an as-converted to common stock basis.

VALENZABIO, INC.
Notes to Financial Statements (Continued)
For the Year Ended December 31, 2021
(*Amounts expressed in thousands, except shares*)

7. Convertible Preferred Stock and Stockholders' Deficit (Continued)

Dividends: Holders of outstanding shares of Series A Preferred Stock shall be entitled to receive dividends (when and if) declared by the Company's board of directors (the "Board of Directors") in preference and prior to the holders of any other series of Preferred Stock and common stock at the rate of eight percent (8.0%) of the original issue price for such series of Preferred Stock per annum ("Preferred Dividend"). Preferred Dividends will not be cumulative. The Company will not declare, pay or set aside dividends to any class of stock (except for dividends payable in shares of common stock to holders of common stock) unless holders of each series of Preferred Stock first receives or simultaneously receive any declared and unpaid Preferred Dividends.

Holders of Preferred Stock are entitled to receive dividends in an amount at least equal to (1) in the case of dividends on common stock or any class or series that is convertible into common stock, that dividend amount per share of Preferred Stock will be determined by multiplying (A) the dividend payable on each share of such class or series as if all shares of such class or series had been converted into common stock and (B) the number of shares of common stock issuable upon conversion of a share of the applicable series of Preferred Stock, in each case calculated on the record date for determination of holders entitled to receive such dividend or (2) in the case of a dividend payable on any class or series that is not convertible into common stock, at a rate per share of Preferred Stock determined by (A) dividing the amount of dividend payable on each share of such class or series of capital stock by the original issuance price of such class or series (subject to adjustments in the event of stock split, stock dividends, combination, etc.) and (B) multiplying the fraction by an amount equal to the original issue price for the Preferred Stock. If the Company declares, pays, or sets aside dividends on the same date on more than one class or series of capital stock, the dividends payable to Preferred Stockholders shall be calculated based on the dividends on the class or series of capital stock that results in the highest Preferred Stock dividend for the applicable series of Preferred Stock.

Liquidation Preference: In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company, holders of Preferred Stock will be entitled to be paid out of the assets of the Company available for distribution to its stockholders on a pari passu basis. In the event of a deemed liquidation event ("DLE"), of the Company, holders of Preferred Stock will be entitled to be paid out of the consideration payable to stockholders in such DLE or out of the available proceeds of the Company on a pari passu basis before any payment is made to the holders of common stock. The amount to be paid will be the greater of (1) the original issue price for the applicable series of Preferred Stock plus any dividends declared but unpaid, or (2) the amount that would have been payable had all shares of the applicable series Preferred Stock been converted into common stock immediately before such event (i.e., liquidation, dissolution, winding up, deemed liquidation event, etc.) ("Applicable Liquidation Amount").

If upon the occurrence of a DLE, the assets of the Company available for distribution to its stockholders shall be insufficient to pay the holders of the Preferred Stock in full, the holders of shares of 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 voluntary or involuntary liquidation, dissolution or winding up of the Company or DLE, after payment of liquidation amounts required to be paid to the holders of Preferred Stock, the remaining assets of the Company available for distribution to its stockholders, or in the case of a DLE, the consideration not payable to the holders of shares of Preferred Stock or the remaining available proceeds, shall be distributed among the holders of the shares of common stock on a pro rata basis.

Conversion Ratio: Each share of Preferred Stock is convertible at the option of the holder at any time into fully paid shares of common stock. The number of shares of common stock convertible into is determined by

7. Convertible Preferred Stock and Stockholders' Deficit (Continued)

dividing the applicable original issue price of the Preferred Stock by the applicable conversion price in effect. Conversion rights terminate in the event of a liquidation, dissolution or winding up of the Company or a DLE. The conversion price will initially be equal to each respective issuance price of $1.99 per share and $8.90 per share for the Series Seed and Series A holders, respectively.

Mandatory Conversion: All outstanding shares of Preferred Stock will automatically convert into shares of common stock, as applicable, at the then-effective conversion price upon the earliest of the following events: (1) The closing of the sale of shares of common stock to the public in a firm-commitment underwritten public offering pursuant to an effective registration statement under the Securities Act of 1933 (the "Securities Act") 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 a majority of the Board of Directors then serving, including approval of any then servicing Series Seed Director (a "Qualified IPO"); (2) the settlement of the initial trade of shares of common stock by means of an effective registration statement under the Securities Act that registers shares of existing capital stock of the Company for resale on the Nasdaq Stock Market's National Market, the New York Stock Exchange or another exchange or marketplace approved a majority of the Board of Directors then serving, including approval of any then serving Series Seed Director (a "Direct Listing"), or (3) the date and time, or the occurrence of an event, specified by vote or written consent of the Requisite Holders (the time of such closing or the date and time specified or the time of the event specified in such vote or written consent is referred to herein as the "Mandatory Conversion Time"), then (i) all outstanding shares of Preferred Stock shall automatically be converted into shares of common stock, and (ii) such shares may not be reissued by the Company.

8. Stock-Based Compensation

2020 Equity Incentive Plan

The Company's 2020 Equity Incentive Plan (the "2020 Plan") was adopted by the Company's board of directors, approved by the Company's stockholder's and became effective in February 2020.

As of December 31, 2021, the Board reserved 3,926,161 shares for issuance under the 2020 Plan.

The 2020 Plan is administered by the Board of Directors. The 2020 Plan provides for the grant of incentive stock options and nonstatutory stock options (collectively, an "Option"), stock appreciation rights ("SARs"), restricted stock awards, restricted stock unit awards and other stock awards (the "Stock Awards"). The Company's employees, directors and consultants are eligible to receive Stock Awards under the 2020 Plan; however, incentive stock options may only be granted to employees.

With the exception of Stock Awards granted to ten percent stockholders, the exercise price of each Option or SAR will not be less than 100% of the fair market value of the common stock subject to the Option or SAR on the date the Stock Award is granted. Notwithstanding the foregoing, an Option or SAR may be granted with an exercise or strike price lower than 100% of the fair market value of the common stock subject to the Stock Award if such Stock Award is granted pursuant to an assumption of or substitution for another option or stock appreciation right pursuant to a corporate transaction and in a manner consistent with the provisions of Section 409A of the Code and, if applicable, Section 424(a) of the Code. Each SAR will be denominated in shares of common stock equivalents. Options and SARs granted under the Company's 2020 Plan are exercisable for a period determined by the Company, but in no event longer than ten years from the date of the grant. A ten

(Amounts expressed in thousands, except shares)

8. Stock-Based Compensation (Continued)

percent stockholder will not be granted an incentive stock option unless the exercise price of such Option is at least 110% of the fair market value on the date of grant and the Option is not exercisable after the expiration of five years from the date of grant.

Under the provisions of ASC 718, stock-based compensation cost is based on the fair value of the portion of stock-based awards that is ultimately expected to vest during the period. The Company utilizes the Black-Scholes option pricing model for determining the estimated fair value for stock-based awards. The Black-Scholes option pricing model requires the use of assumptions which determine the fair value of the stock-based awards. Determining the fair value of stock-based awards at the grant date requires significant judgment, including estimating the expected term of stock options, the expected volatility of the Company's stock and expected dividends. The Company's policy is to account for forfeitures when they occur by reversing compensation costs when the award is forfeited.

The Company does not have a history of market prices of its common stock and, as such, volatility is estimated using historical volatilities of similar public companies. The expected term of awards is estimated based on the simplified method, which calculates the expected term based upon the midpoint of the term of the award and the vesting period.

As of December 31, 2021, there were 321,396 shares available to be granted under the 2020 Plan.

A summary of the status of the Company's stock option activity for the year ended December 31, 2021 is presented in the table and narrative below:

	2021	
	Options	Weighted-Average Exercise Price
Outstanding at January 1, 2021	183,842	$ 0.34
Granted	1,194,737	2.51
Exercised	(14,327)	0.34
Forfeited	(9,145)	0.34
Cancelled	(7,526)	2.26
Outstanding at December 31, 2021	1,347,581	$ 2.26
Options exercisable at December 31, 2021	409,363	$ 1.63
Options vested and expected to vest at December 31, 2021	1,337,581	$ 2.26

The weighted-average grant-date fair value of options granted during the year ended December 31, 2021 was $1.77.

The weighted-average remaining contractual life is 8.7 years for options exercisable and 9.2 years for options vested and expected to vest as of December 31, 2021.

As of December 31, 2021, the total compensation cost related to options not yet recognized in the financial statements is approximately $1.6 million, and the weighted-average period over which it is expected to be recognized is 2.0 years.

VALENZABIO, INC.
Notes to Financial Statements (Continued)
For the Year Ended December 31, 2021
(*Amounts expressed in thousands, except shares*)

8. Stock-Based Compensation (Continued)

The assumptions used to value options granted are as follows:

	For the Year Ended December 31, 2021
Expected term of option	5.3 – 5.8 years
Expected volatility	84% – 88%
Risk free interest rate	0.6% – 1.3%
Expected dividend yield	0%

A summary of the status of the Company's nonvested restricted common stock awards at December 31, 2021 and changes during the year ended December 31, 2021 was as follows:

	Shares	Weighted - Average Grant Date Fair Value
Unvested restricted stock awards outstanding at January 1, 2021	6,164,203	$ 0.00
Shares granted	—	—
Shares vested	2,324,685	0.00
Unvested restricted stock awards outstanding at December 31, 2021	3,763,860	$ 0.00

As of December 31, 2021, there was unrecognized stock-based compensation expense related to unvested restricted stock units of $0.3 million, which the Company expects to recognize over a weighted-average period of approximately 2.2 years.

Total stock-based compensation expense recorded in the accompanying statement of comprehensive loss for the year ended December 31, 2021 was $0.6 million.

The Company recorded no tax benefit related to these options as the Company is currently in a net operating loss position and maintains a full valuation allowance.

Stock-based compensation expense is included in research and development and general and administrative expense as follows:

	For the Year Ended December 31, 2021
Research and development	$ 369
General and administrative	271
Total	$ 640

9. Commitments and Contingencies

From time to time, in the ordinary course of business, the Company may be subject to litigation and regulatory examinations as well as information gathering requests, inquiries and/or investigations. The Company

(Amounts expressed in thousands, except shares)

9. Commitments and Contingencies (Continued)

does not believe it is currently subject to any material matters where there is at least a reasonable possibility that a material loss may be incurred.

10. Income Taxes

There is no provision for income taxes because the Company has historically incurred operating losses and maintains a full valuation allowance against its net deferred tax assets. The significant components of the Company's tax provision on December 31, 2021 are shown below.

	December 31, 2021
Provision/(Benefit):	
Federal	$ (8,184)
State	(2,552)
Valuation allowance	10,736
Total provision/(benefit)	$ —

A reconciliation of the statutory tax rates to the effective tax rates is as follows:

	Year Ended December 31, 2021
Federal statutory rate	21.0%
State tax, net of federal benefit	6.6%
Tax credits	0.7%
Stock-based compensation	(0.1)%
Valuation allowance	(28.2)%
	0.0%

Future tax benefits (deferred tax assets) related to temporary differences are as follows:

	December 31, 2021
Gross deferred tax assets:	
Net operating losses	$ 8,244
Tax credits (federal and state)	256
Stock-based compensation	136
Capitalized license agreements	4,435
Other	40
	$ 13,111
Less—Valuation allowance	(13,111)
Net deferred tax asset	$ —

The Company has a full valuation allowance against its deferred tax assets, since, in the opinion of management, based upon the history of losses by the Company and insufficient future federal and state taxable

(Amounts expressed in thousands, except shares)

10. Income Taxes (Continued)

income; it is more likely than not that the benefits will not be realized. All or a portion of the remaining valuation allowance may be reduced in future years based on an assessment of earnings sufficient to fully utilize these potential tax benefits.

At December 31, 2021, the Company had the following net operating loss ("NOL") and credit carryforwards available:

	As of December 31, 2021
Federal net operating loss carryforwards	$ 26,899
State net operating loss carryforwards	31,759
Federal research and development credit carryforwards	256
State research and development credit carryforwards	—

Utilization of the NOL's and research tax credit carryforwards may be subject to a substantial annual limitation due to ownership limitations that have occurred or that could occur in the future, as required under Section 382 of the Internal Revenue Code of 1986, as well as similar state provisions. These ownership changes may limit the amount of the NOL and research credit carryforwards that can be utilized annually to offset future taxable income and tax, respectively. In general, an "ownership change" as defined by Section 382 of the Code results from a transaction or series of transactions over a three-year period resulting in an ownership change of more than 50 percentage points of the outstanding stock of a by certain stockholders or public groups. If the Company has experienced a change of control at any time since the Company's formation, utilization of its net operating losses or research and development credit carryforwards would be subject to an annual limitation. Any limitation may result in expiration of a portion of the net operating loss or research and development credit carryforwards before utilization which would reduce the Company's gross deferred tax assets. Accordingly, even if we attain profitability, we may not be able to utilize a material portion of our NOLs or credits. Under the Tax Cuts and Jobs Act of 2017 the treatment of NOL's arising on or after January 1, 2018, and beyond may only be used to offset 80% of taxable income. This change may require us to pay federal income taxes in future years despite generating a loss for federal income tax purposes in prior years.

ASC 740 addresses the determination of whether tax benefits claimed or expected to be claimed on a tax return should be recorded in the financial statements. Under ASC 740, the Company may recognize the tax benefit from an uncertain tax position only if it is more likely that not that the tax position will be sustained on examination by the taxing authorities, based on the technical merits of the position. The Company has no material uncertain tax positions that qualify for either recognition or disclosure in its financial statements.

It is the Company's policy to recognize interest and/or penalties related to income tax matters in income tax expense. As of December 31, 2021, the Company has not accrued any interest and penalties related to uncertain tax positions. The Company does not have any outstanding U.S. federal income tax or material state and local tax matters for periods through December 31, 2021. There are no federal or state and local income tax returns currently under examination. The Company's tax returns from inception to date are subject to examination by the taxing authorities.

VALENZABIO, INC.
Notes to Financial Statements (Continued)
For the Year Ended December 31, 2021
(*Amounts expressed in thousands, except shares*)

12. Subsequent Events

The Company has evaluated all events subsequent to December 31, 2021, through April 29, 2022, which represents the date these financial statements were available to be issued. The Company is not aware of any subsequent events that would require recognition or disclosure to the financial statements other than as described below.

Novelty Nobility License and Commercialization Agreement

In February 2022, the Company entered into an exclusive license agreement with Novelty Nobility (the "Novelty License Agreement") to obtain a worldwide exclusive license for the development and commercialization of NN2802, an unmodified immunoglobulin G1 (IgG1) monoclonal antibody, as a therapeutic treatment.

Under the terms of the Novelty License Agreement, the Company will have exclusive rights to develop and commercialize products containing NN2802. The Company will undertake all development, regulatory and commercialization activities. In consideration of the exclusive license, the Company made an upfront payment of $7.0 million. Additional payments related to development and regulatory milestones may be up to $44.3 million and commercial sales milestones may be up to $682.0 million. Further, tiered, low- to high-single digit royalties on future net sales may be made.

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Shares

Class A Common Stock

PROSPECTUS

Morgan Stanley *Jefferies* *Cowen* *Piper Sandler*

Through and including , 2023 (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.

, 2023

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Unless otherwise indicated, all references to "ACELYRIN," the "company," "we," "our," "us" or similar terms refer to ACELYRIN, INC.

Item 13. Other Expenses of Issuance and Distribution.

The following table sets forth all expenses to be paid by us, other than underwriting discounts and commissions, in connection with this offering. All amounts shown are estimates except for the Securities and Exchange Commission (the SEC) registration fee, the Financial Industry Regulatory Authority, Inc. (FINRA) filing fee and The Nasdaq Global Market (Nasdaq) listing fee.

	Amount Paid or to Be Paid
SEC registration fee	$ *
FINRA filing fee	*
Nasdaq listing fee	*
Printing and engraving expenses	*
Legal fees and expenses	*
Accounting fees and expenses	*
Custodian transfer agent and registrar fees	*
Miscellaneous expenses	*
Total	$ *

* To be provided by amendment.

Item 14. Indemnification of Directors and Executive Officers.

Section 145 of the DGCL, authorizes a court to award, or a corporation's board of directors to grant, indemnity to directors and executive officers in terms sufficiently broad to permit such indemnification under certain circumstances for liabilities, including reimbursement for expenses incurred, arising under the Securities Act. Our amended and restated certificate of incorporation that will be in effect immediately prior to the closing of this offering permits indemnification of our directors, officers, employees and other agents to the maximum extent permitted by the DGCL, and our amended and restated bylaws that will be in effect on the closing of this offering provide that we will indemnify our directors and executive officers and permit us to indemnify our employees and other agents, in each case to the maximum extent permitted by the DGCL.

We have entered into indemnification agreements with our directors and executive officers, whereby we have agreed to indemnify our directors and executive officers to the fullest extent permitted by law, including indemnification against expenses and liabilities incurred in legal proceedings to which the director or executive officer was, or is threatened to be made, a party by reason of the fact that such director or executive officer is or was a director, executive officer, employee, or agent of ACELYRIN, provided that such director or executive officer acted in good faith and in a manner that the director or executive officer reasonably believed to be in, or not opposed to, the best interest of ACELYRIN.

At present, there is no pending litigation or proceeding involving a director or executive officer of ACELYRIN regarding which indemnification is sought, nor is the registrant aware of any threatened litigation that may result in claims for indemnification.

We maintain insurance policies that indemnify our directors and officers against various liabilities arising under the Securities Act and the Securities Exchange Act of 1934, as amended, that might be incurred by any director or officer in his capacity as such.

The underwriters are obligated, under certain circumstances, under the underwriting agreement to be filed as Exhibit 1.1 to this Registration Statement, to indemnify us and our officers and directors against liabilities under the Securities Act.

Item 15. Recent Sales of Unregistered Securities.

Set forth below is information regarding unregistered securities issued by us since our inception in July 2020.

Equity Plan-Related Issuances

1. From December 9, 2020 to December 5, 2022, we granted to certain of our directors, employees and consultants options to purchase 10,997,888 shares of our Class A Common Stock with per share exercise prices ranging from $0.3896 to $2.98 under the 2020 Plan.
2. From March 8, 2022 to November 21, 2022, we granted to certain of our directors and officers restricted stock units (RSUs) for an aggregate of 2,183,426 shares of our Class A Common Stock under the 2020 Plan.
3. From January 20, 2022 to March 8, 2022, we granted to certain of our directors and officers an aggregate of 983,912 shares of our Class A Common Stock in connection with restricted stock awards granted under the 2020 Plan.
4. On October 29, 2021 we issued to certain of our employees an aggregate of 40,000 shares of our Class A Common Stock at a per share purchase prices ranging of $0.3896 pursuant to exercises of options under the 2020 Plan for an aggregate purchase price of $15,584.00.
5. On January 4, 2023, in connection with the Acquisition, we assumed options of ValenzaBio optionholders which are now exercisable for an aggregate of 2,464,653 shares of our Class A Common Stock.

Other Issuances of Capital Stock

6. On July 31, 2020, we issued to certain of our directors and officers 5,600,000 shares of Class A Common Stock for an aggregate purchase price of $60.00.
7. In a closing held on October 9, 2020, we issued and sold an aggregate of 8,000,000 shares of our Series A redeemable convertible preferred stock at a purchase price of $1.00 per share for an aggregate purchase price of $8,000,000.00.
8. In multiple closings held between October 19, 2021 and February 4, 2022, we issued and sold an aggregate of 48,230,900 shares of our Series B redeemable convertible preferred stock at a purchase price of $5.1834 per share for an aggregate purchase price of $250,000,047.06.
9. In a closing held on September 9, 2022, we issued and sold an aggregate of 24,115,368 shares of our Series C preferred stock at a purchase price of $6.2201 per share for an aggregate purchase price of $150,000,000.50.
10. On January 4, 2023, we issued 37,242,709 shares of our Class A Common Stock in connection with the Acquisition.

The offers, sales and issuances of the securities described in paragraphs (1) through (5) were deemed to be exempt from registration under Rule 701 promulgated under the Securities Act as transactions under compensatory benefit plans and contracts relating to compensation, or under Section 4(a)(2) of the Securities Act as a transaction by an issuer not involving a public offering. The recipients of such securities were our directors, employees or bona fide consultants and received the securities under our equity incentive plans. Appropriate

legends were affixed to the securities issued in these transactions. Each of the recipients of securities in these transactions had adequate access, through employment, business or other relationships, to information about us.

The offers, sales and issuances of the securities described in paragraphs (6) through (10) were deemed to be exempt under Section 4(a)(2) of the Securities Act or Rule 506 of Regulation D under the Securities Act as a transaction 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 investor within the meaning of Rule 501 of Regulation D under the Securities Act and had adequate access, through employment, business or other relationships, to information about us. No underwriters were involved in these transactions.

Item 16. Exhibits and Financial Statement Schedules.

(a) Exhibits.

Exhibit Number	Description
1.1+	Form of Underwriting Agreement.
2.1+*	Agreement and Plan of Merger and Reorganization by and among the Registrant, ValenzaBio, Inc., WH1, Inc., WHZ, LLC and Seller Representatives LLC dated December 20, 2022.
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 immediately prior to the closing of the offering.
3.3+	Bylaws of the Registrant, as currently in effect.
3.4+	Form of Amended and Restated Bylaws of the Registrant, to be in effect immediately after the closing of the offering.
4.1+	Form of Common Stock Certificate of the Registrant.
4.2+	Amended and Restated Investors' Rights Agreement, by and among the Registrant and certain of its stockholders, dated September 9, 2022.
5.1+	Opinion of Cooley LLP.
10.1+#	ACELYRIN, INC. 2020 Stock Option and Grant Plan, as amended.
10.2+#	Forms of Non-Qualified Stock Option Grant Notice, Non-Qualified Stock Option Grant Notice-Non-U.S., Early Exercise Non-Qualified Stock Option Grant Notice, Incentive Stock Option Grant Notice, Restricted Stock Award Notice, Stock Option Agreement and Notice of Exercise and Early Exercise Stock Purchase Agreement under the ACELYRIN, INC. 2020 Stock Option and Grant Plan.
10.3+#	ACELYRIN, INC. 2023 Equity Incentive Plan.
10.4+#	Forms of Stock Option Grant Notice, Stock Option Agreement and Notice of Exercise under the ACELYRIN, INC. 2023 Equity Incentive Plan.
10.5+#	Forms of Restricted Stock Unit Grant Notice and Award Agreement under the ACELYRIN, INC. 2023 Equity Incentive Plan.
10.6+#	ACELYRIN, INC. 2023 Employee Stock Purchase Plan.
10.7+#	ValenzaBio Inc. Stock Plan and forms thereunder.

Exhibit Number	Description
10.8+#	ACELYRIN, INC. 2023 Non-Employee Director Compensation Policy.
10.9+#	ACELYRIN, INC. Severance Plan.
10.10+#	Form of Indemnification Agreement by and between the Registrant and its directors and executive officers.
10.11+#	Form of Employment Agreement for Executive Officers.
10.12+*	License and Collaboration Agreement by and between the Registrant and Affibody AB, dated August 9, 2021, as amended.
10.13+*	License and Commercialization Agreement by and between the ValenzaBio Inc. and Pierre Fabre Medicament SAS, dated March 25, 2021, as amended.
21.1+	List of Subsidiaries.
23.1+	Consents of PricewaterhouseCoopers LLP, independent registered public accounting firm.
23.2+	Consent of Macias Gini & O'Connell LLP, independent auditor.
23.2+	Consent of Cooley LLP (included in Exhibit 5.1).
24.1+	Power of Attorney (included on signature page).
107+	Filing Fee Table.

+ To be filed by amendment.
* Portions of this exhibit (indicated by [*]) have been omitted because the registrant has determined that the information is both not material and is the type that the Registrant treats as private or confidential.
Indicates management contract or compensatory plan.
† Previously filed.

(b) Financial Statement Schedules.

All financial statement schedules are omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or the notes thereto.

Item 17. Undertakings.

(a) The undersigned registrant hereby undertakes to provide to the underwriters at the closing specified in the underwriting agreement certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

(b) Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant under the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the U.S. 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.

(c) The undersigned registrant 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 on Rule 430A and contained in a form of prospectus filed by the registrant under Rule 424(b)(1) or (4) or 497(h) under the Securities Act will 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 of 1933, as amended, each post-effective amendment that contains a form of prospectus will be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time will be deemed to be the initial bona fide offering thereof.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Agoura Hills, California on , 2023.

ACELYRIN, INC.

By: _____
Name: Shao-Lee Lin, M.D., Ph.D.
Title: Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Shao-Lee Lin, Mardi C. Dier and Mina Kim and each one of them, as his or her true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him or her and in their name, place and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this registration statement, and to sign any registration statement for the same offering covered by this registration statement that is to be effective on filing pursuant to Rule 462(b) under the Securities Act of 1933, as amended, and all post-effective amendments thereto, and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents or any of them, or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, as amended, this registration statement has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
Shao-Lee Lin, M.D., Ph.D.	Founder, Chief Executive Officer and Director (*Principal Executive Officer*)	, 2023
Mardi C. Dier	Chief Financial Officer and Chief Business Officer (*Principal Financial and Accounting Officer*)	, 2023
Bruce C. Cozadd	Director	, 2023
Dan Becker, M.D., Ph.D.	Director	, 2023
Alan B. Colowick, M.D., M.P.H.	Director	, 2023
Patrick Machado, J.D.	Director	, 2023
Beth Seidenberg, M.D.	Director	, 2023
Dawn Svoronos	Director	, 2023