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

FORM 10-K

(Mark One)

x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2023

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission file number 001-04321

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)

4149 Liberty Canyon Road Agoura Hills, California	**91301**
(Address of Principal Executive Offices)	(Zip Code)

(805) 730-0360
Registrant's telephone number, including area code

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	SLRN	The Nasdaq Stock Market LLC

Securities registered pursuant to section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.Yes o No x

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.Yes o No x

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports); and (2) has been subject to such filing requirements for the past 90 days. Yes x No o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this

chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No o

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

Large accelerated filer	o	Accelerated filer	o
Non-accelerated filer	x	Smaller reporting company	o
		Emerging growth company	x

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 13(a) of the Exchange Act. o

Indicate by check mark whether the registrant has filed a report on and attestation to its management’s assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. o

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. o

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant’s executive officers during the relevant recovery period pursuant to §240.10D-1(b). o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes o No x

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant, computed by reference to the closing price as of the last business day of the registrant’s most recently completed second fiscal quarter, June 30, 2023, was approximately $1,458.2 million. Shares of common stock held by each executive officer and director have been excluded since such persons may be deemed affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

The number of shares of common stock outstanding as of March 25, 2024 was 98,365,050.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's Definitive Proxy Statement relating to the Annual Meeting of Stockholders, which will be filed with the Securities and Exchange Commission within 120 days after the end of the Registrant's fiscal year ended December 31, 2023, are incorporated by reference into Part III of this Report.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K for the year ended December 31, 2023 ("Annual Report") contains forward-looking statements that involve substantial risks and uncertainties. The forward-looking statements are contained principally in the sections titled “Risk Factors,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” “Business” and elsewhere in this Annual Report. 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 and clinical trials, results of preclinical 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 Annual Report 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 or any other product candidates we may develop, including additional indications that we may pursue;
- the characteristics, safety, tolerability and efficacy of izokibep, lonigutamab 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 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 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 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 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 or any other product candidates we may develop, as well as the pricing and reimbursement of izokibep, lonigutamab or any other product candidates we may develop, if approved;
- our continued reliance on third parties to conduct clinical trials of izokibep, lonigutamab 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 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, contract manufacturing organizations ("CMOs"), collaborators, contract research organizations ("CROs") and employees; and
- our expectations regarding the period during which we will qualify as an emerging growth company under the JOBS Act.

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 Annual Report and are subject to a number of risks, uncertainties and assumptions described in the section titled “Risk Factors” and elsewhere in this Annual Report. 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 Annual Report, 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 Annual Report, 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.

SUMMARY RISK FACTORS

Below is a summary of material factors that make an investment in our securities speculative or risky. Importantly, this summary does not address all of the risks that we face. Additional discussion of the risks and uncertainties summarized in this risk factor summary, as well as other risks that we face, follows this summary. This summary is qualified in its entirety by that more complete discussion of such risks and uncertainties.

- We are a clinical stage biopharma company with a limited operating history, no products approved for commercial sale, have incurred substantial losses since our inception and anticipate incurring substantial and increasing losses for the foreseeable future.
- 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 ongoing and planned Phase 3 clinical trials of izokibep, 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 expect to engage in strategic transactions in the future, which could impact our liquidity, increase our expenses and present significant distractions to our management.
- We have been named a defendant in a purported securities class action lawsuit. This could result in substantial damages, divert management's time and attention from our business, and have a material adverse effect on our financial and operational results.
- 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, certain of which remain unremediated. 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 common stock.

PART I

Item 1. 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."

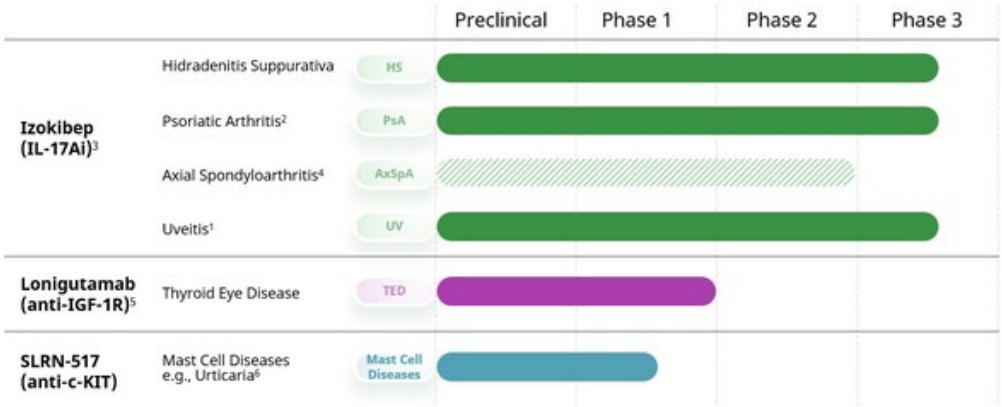
Our initial focus is on the treatment of diseases with pathology related to excess activation of the immune system, an area where our management and team bring industry-leading expertise. We acquired our portfolio of product candidates with the intent to develop and commercialize novel therapies that we believe may 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, 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 plan to utilize the results from initial clinical trials and the learnings we obtain from emerging biology to potentially expand the application of our candidates to other indications in which there are significant unmet needs.

Our Product Candidates and Pipeline

Our current portfolio consists of multiple product candidates being investigated across several indications.

Our lead product candidate, izokibep, is being evaluated in multiple immunologic indications, including hidradenitis suppurativa (HS), psoriatic arthritis (PsA), and uveitis. We are also developing lonigutamab for the treatment of thyroid eye disease ("TED"), as well as are developing SLRN-517 in chronic urticaria.

The following chart summarizes the status of our current pipeline:



(1) Phase 2b/3 trial in Uveitis.
(2) Phase 2b/3 trial in PsA.
(3) Excludes (i) development, commercialization and manufacturing rights in mainland China, Hong Kong, Macau, South Korea and Taiwan, and (ii) development rights in certain other Asia Pacific countries including, without limitations, Australia, India, New Zealand and Singapore. We retain decision making authority for izokibep global development.
(4) Based on data from our Phase 2 and ongoing Phase 2b/3 trials in PsA, we intend to discuss with the FDA initiation of the Phase 3 program in AxSpA without completing earlier clinical trials in AxSpA. The FDA may require us to complete a Phase 2 trial in AxSpA prior to initiating our planned Phase 3 program.
(5) Worldwide rights to non-oncology indications.
(6) Based on preclinical studies demonstrating highly potent inhibition of the c-KIT pathway targeting mast cell proliferation and degranulation, our first indication of interest for SLRN-517 is chronic urticaria.

Leadership

Our company is led by Shao-Lee Lin, M.D., Ph.D., our Founder and Chief Executive Officer. Dr. Lin is joined by a team of veteran biopharma executives who together bring strong track records of identifying, acquiring, and then developing and commercializing medicines.

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.** We believe izokibep is a “pipeline-in-a-program”, which reflects our strategy to develop a single asset in multiple indications. Izokibep is in clinical trials for HS, PsA, and uveitis. 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, such as AxSpa.
- **Advance lonigutamab for the treatment of TED.** We intend to advance lonigutamab, an anti-IGF-1R in development for the subcutaneous treatment of TED, to provide potentially differentiated safety profile, clinical response and dosing convenience over existing therapies.
- **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 SLRN-517, a fully human monoclonal antibody designed to target a distinct epitope of c-KIT, for the treatment of chronic urticaria.
- **Diversify our portfolio with new product candidates**. We aim 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 have and will continue to strategically evaluate potential licensing partnerships and other collaborations to maximize the value of our portfolio, or to broaden 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 in certain key geographical markets, becoming an integrated biopharma company. 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.

Our Development Programs

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 high potency and the potential for robust tissue penetration due to its small molecular size, about one-tenth the size of a monoclonal antibody.

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. Within the IL-17 family, 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, 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.

Development

Izokibep is currently being evaluated in multiple late-stage clinical trials in moderate-to-severe hidradenitis suppurativa (HS), moderate-to-severe psoriatic arthritis (PsA), and non-infectious uveitis, with plans to initiate an additional Phase 3 program in axial spondyloarthritis (AxSpA).

Izokibep for the Treatment of Moderate-to-Severe Hidradenitis Suppurativa (HS)

HS is a severe autoimmune condition where the hallmark of disease is skin abscesses, inflammatory nodules, fistulae and scar tissue. 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.

Izokibep has advanced to Phase 3 development in moderate-to-severe HS. In September 2023, we announced topline data from Part B of the multicenter, randomized, placebo-controlled, double-blind Phase 2b trial of izokibep in moderate-to-severe HS ("Phase 2b HS Trial") in North America and Europe. The primary endpoint of the Phase 2b HS Trial was not met, which was HiSCR75 a measure which represents a 75% improvement in abscesses and inflammatory nodules without worsening in either of these individually, or worsening in tunneling, at week 16. After week 16, participants that previously received placebo were dosed with 160mg izokibep on either a QW or Q2W dosing schedule until the end of the treatment period at week 32. In March 2024, we announced long-term (week 32) data from such trial, in which we observed rapid dose-ordered improvement across certain disease manifestations including HiSCR90 and HiSCR100 response rates. The Phase 2b is not a registrational trial, and we will need to conduct two Phase 3 trials in moderate-to-severe HS as part of any potential BLA submission.

We are currently conducting a global Phase 3 pivotal trial in moderate-to-severe HS.

Izokibep for the Treatment of Psoriatic Arthritis (PsA)

PsA is a chronic immune-mediated inflammatory disease characterized by both joint inflammation and skin lesions consistent with psoriasis (PsO). PsA causes pain, stiffness and swelling in and around the joints. Common symptoms include arthritis, skin lesions and enthesitis.

Our Phase 2b/3 Trial of Izokibep in PsA

We are currently conducting a multicenter randomized, placebo-controlled, double-blind Phase 2b/3 trial of izokibep in moderate-to-severe PsA in North America and Europe. The primary endpoint was a measure of ACR50 response, defined as a 50% improvement in tender and swollen joints, along with improvement in three of these five parameters: (a) patient global assessment of disease activity; (b) physician global assessment of disease activity; (c) patient pain scale; (d) disability/functional questionnaire and (e) decreased concentration of C-reactive protein correlated to inflammation, at week 16. In March 2024, we announced positive topline results from such trial, including that the primary endpoint ACR50 was met with statistical significance. In this trial, after 16 weeks, participants that previously received placebo receive izokibep for the remainder of the 52-week trial period.

The long-term follow up period of the Phase 2b/3 trial in PsA is ongoing.

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. 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.

We believe the data from our trials in PsA can be informative for AxSpA, since PsA and AxSpA have many overlapping disease features, including enthesitis, arthritis, and spinal involvement and fall under the same umbrella classification of “spondyloarthropathies” thought to have an overlapping pathogenesis. We intend to discuss with the FDA initiation of a Phase 3 program in AxSpA without completing earlier clinical trials in AxSpA. However, the FDA has not yet approved our plans to initiate Phase 3 clinical trials in AxSpA and may require that we first complete a Phase 2 trial in AxSpA.

Izokibep for the Treatment of Uveitis

Uveitis is an inflammatory disease of the eye that sometimes arises in association with other immune-related diseases. Patients affected by uveitis are at risk of permanent visual impairment.

Based on our existing clinical data from izokibep in other indications and clinical data from other approved therapies, following discussion with the FDA, we are currently conducting 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. The trial is expected to enroll participants with non-infectious uveitis involving the intermediate, posterior or pan uveitis segments. Outcomes of this trial will be assessed at 24 weeks by comparing worsening of those on placebo as compared to izokibep 160 mg QW as the primary endpoint.

This trial is ongoing and no results are available at this time. We have not previously completed any clinical trials for uveitis. Once the data from the current Phase 2b/3 trial is available, we intend to engage in discussions with the FDA and the EMA on the need for one or more additional Phase 3 trials to support a BLA submission in this indication.

Safety Profile of Izokibep

Izokibep has been administered to more than 1000 participants, and in some for up to three years. Izokibep has been generally well-tolerated in trials conducted by us to date, with the most common adverse event being injection site reactions (ISRs), which include redness, pain and swelling at the injection site. The majority of ISRs observed in our clinical trials have been graded mild-to-moderate in severity. We have observed some trial participant discontinuations due to ISRs, among other discontinuation factors. We have observed other adverse events, including serious adverse events (SAEs), in certain clinical trials of izokibep, which have included, without limitation, SAEs relating to gastrointestinal symptoms.

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 being investigated for the treatment of thyroid eye disease (TED). We currently hold exclusive worldwide development and commercialization rights to lonigutamab outside of oncology, which oncology rights are held by Pierre Fabre.

Lonigutamab in Thyroid Eye Disease (TED)

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. 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).

In March 2024, we announced that cohort 1 of our Phase 1/2 trial in TED achieved proof-of-concept. The Phase 1/2 trial is ongoing, and tests several subcutaneous dose levels and uses three to four doses to obtain an early safety profile for lonigutamab in TED participants. While the trial is not large enough to show statistical benefits over placebo, participants are assessed for reduction in eye bulging (proptosis), a common finding in patients with moderate to severe TED.

Lonigutamab was generally well-tolerated. There were no reported serious adverse events and no discontinuations in patients treated with lonigutamab in cohort 1 and the open-label cohort 2 data cut (six patients reached six-week visit).

We believe these data from the Phase 1/2 trial and a Phase 1a single-ascending dose (SAD) trial support lonigutamab's the ability to saturate receptor occupancy and exceed target-mediated drug disposition with a subcutaneous dose of lonigutamab, suggesting that the characteristics of lonigutamab enable subcutaneous delivery which allows for reduction of maximum serum concentration (Cmax) incurred with current IV therapies. Decreasing Cmax may lessen the potential for breach of the blood labyrinth barrier and limit IGF-1R inhibition in the neural tissues of the inner ear. In addition to potentially decreasing the side effect of hearing impairment, we hypothesize these characteristics of lonigutamab may also enable evaluation for improved depth and durability of clinical response.

We plan to commence a Phase 2b/3 trial in TED in the second half of 2024.

SLRN-517 in Chronic Urticaria

We are also developing SLRN-517, a fully IgG1 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. We are in the early stages of exploring the potential of SLRN-517 for 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.

License and Collaboration Agreements

License and Collaboration Agreement with Affibody

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 consolidated statements 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. In November 2023, the Company paid a total amount of $15.0 million in relation with attaining one of the development milestones described above and recorded the payment within research and development expenses in the consolidated statement of operations and comprehensive loss for the year ended December 31, 2023. Royalties will be recognized as cost of sales when products are sold and royalties are payable. No other milestone or royalties were probable and estimable as of December 31, 2023 and 2022.

License and Commercialization Agreement with Pierre Fabre

We acquired ValenzaBio, Inc. (ValenzaBio) in an all stock transaction on January 4, 2023 (the Acquisition). Upon the closing of the Acquisition, the Company became the successor to ValenzaBio's rights under the March 25, 2021 license and commercialization agreement between ValenzaBio and Pierre Fabre, as amended (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. The 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 the Company from using the licensed intellectual property in any antibody drug conjugate, multi-specific antibodies or any other derivatives of lonigutamab.

In the event the Company decides 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 the Company has the right of first negotiation to acquire such development and commercialization rights as to that territory, or Pierre Fabre has the right to require the Company to buy out its right to the option for a one-time payment of $31.0 million or the Company has 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 the Company buys out Pierre Fabre's right to the option, the option will expire or terminate, respectively. The Company is 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 consideration for the amendment to the Pierre Fabre Agreement, which became effective upon the closing of the Acquisition (see Note 3 to our consolidated financial statements entitled "ValenzaBio Acquisition" in this Annual Report on Form 10-K), the Company paid Pierre Fabre an aggregate license payment of $10.0 million. The Company is 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 the Company enters into a sublicense with a third party, the Company 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 relates to.

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 the Company or any of its affiliates institutes a patent challenge against the licensed patents from Pierre Fabre. The Company 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. As of December 31, 2023, no milestones were probable and accrued in the consolidated balance sheet. The payment of $10.0 million for additional license fees was recorded as research and development expenses in the consolidated statement of operations and comprehensive loss for the year ended December 31, 2023.

Novelty Nobility License and Commercialization Agreement

In January 2023, we became the successor to an exclusive license agreement with Novelty Nobility (the "Novelty License Agreement") and obtained a worldwide exclusive license for the development and commercialization of SLRN-517, an unmodified IgG1 monoclonal antibody, as a therapeutic treatment.

For further detail on our license and collaboration Agreements, see Note 6 to our consolidated financial statements entitled "Significant Agreements" in this Annual Report on Form 10-K.

Intellectual Property

Intellectual property is critical to our business. 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 developed internally and/or licensed from our collaborators or other third parties. Since patent protection is a territorial right, we seek to protect our proprietary position by, among other methods, filing patent applications in the United States and in other major pharmaceutical markets outside of the United States. We have in-licensed and procured patents and patent applications, which include claims directed to compositions covering our product candidates and methods of using and manufacturing such compositions. As of March 25, 2024, our owned and exclusively licensed patent portfolio included nine issued U.S. patents, 143 issued foreign patents, eight pending provisional U.S. patent applications, two pending non-provisional U.S. patent applications, four pending Patent Cooperation Treaty (PCT) applications and 52 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 SLRN-517.

Izokibep

With respect to izokibep, as of March 25, 2024, we exclusively in-licensed six issued U.S. patents, one pending U.S. non-provisional application, 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. 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 ("Fees"). In addition, as of March 25, 2024, we also own two pending PCT applications directed to methods of treatment of ailments by administration of izokibep. Patents, if issued from these PCT applications, assuming a U.S. national stage entry from these PCT applications, 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 Fees. Moreover, as of March 25, 2024, we owned seven pending U.S. provisional patent applications directed to methods of treatment of ailments by administration of izokibep. Should those issue as U.S. patents, they are expected to expire between 2044 to 2045, without giving effect to any potential patent term extensions and patent term adjustments and assuming payment of all appropriate Fees.

Lonigutamab

With respect to lonigutamab, as of March 25, 2024, we exclusively in-licensed from Pierre Fabre two issued U.S. patents, at least 42 corresponding foreign patents and at least 19 foreign patent applications directed to composition of matter. Such issued patents are expected to expire in 2035, without taking into account any possible patent term adjustment

or extensions and assuming payment of all appropriate Fees. The portfolio further includes one pending PCT application and one pending provisional application filed by us. Patents, if issued from these pending applications (assuming conversion with a subsequent U.S. national stage application) are expected to expire in 2043 or 2045, respectively, without giving effect to any potential patent term extensions and patent term adjustments, and assuming payment of all appropriate Fees.

SLRN-517

With respect to SLRN-517, as of March 25, 2024, we exclusively in-licensed one issued U.S. patent, two pending non-provisional U.S. patent applications, one pending PCT application, and 15 pending foreign applications directed to composition of matter and/or method of treatment, from Novelty Nobility, Inc. The issued U.S. patent is expected to expire in 2038, without taking into account any possible patent term adjustment or extensions and assuming payment of all appropriate Fees. The pending non-provisional U.S. patent applications, should they issue as U.S. patents, are expected to expire between 2038 and 2040, without taking into account any possible patent term adjustment or extensions and assuming payment of all appropriate Fees. Patents, if issued from the pending PCT application, assuming a U.S. national stage entry, are expected to expire in 2042, without taking into account any possible patent term adjustment or extensions and assuming payment of all appropriate Fees. We do not currently own or license any issued patents with claims directed to SLRN-517 and there can be no assurance that we will obtain any issued patents directed to SLRN-517.

The patent positions of biotechnology companies are complex and uncertain. There can be no assurance that our patents, even once issued, will be held valid and enforceable in a court of law, or provide more than a short period of protection prior to their expiration. Third parties such as competitors could design around our patents or assert claims of infringement against us with regard to their proprietary rights. Such claims might be costly and time consuming to defend, and result in an injunction or equitable relief impacting our ability to develop or commercialize our product candidates. 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 obtain and maintain our licenses to use intellectual property owned by third parties; and to defend and enforce our proprietary rights, including our patents. For more information regarding the risks related to our intellectual property, see Item 1A. Risk Factors --"Risks Related to Intellectual Property".

The term of individual patents in most countries is twenty years from the earliest non-provisional patent application filing priority date (assuming all patent maintenance fees are paid). Patent terms can be increased or decreased in certain instances, depending on the jurisdiction that issued the patent and laws and regulations of such country. For example, in the United States, the term of a patent that covers an FDA-approved drug may be eligible for a patent term extension of up to five years (subject to exceptions) under the Hatch-Waxman Act, which is designed to compensate for the patent term lost during the FDA regulatory review process. Similar provisions are available in Europe and certain other foreign jurisdictions to extend the term of a patent that covers an approved drug.

We assess the extent to which we may seek patent protection for aspects of our product engine. 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.

We also rely on trade secret protection for our confidential information and proprietary know-how to develop, strengthen and maintain any competitive advantage in the field of immunology. Trade secrets are, however, difficult to protect and no assurance can be given that we can meaningfully protect our trade secrets. Other parties could independently develop substantially equivalent proprietary and confidential information, or otherwise disclose or gain access to our trade secrets. 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 obtain and maintain our licenses to use intellectual property owned by third parties; and to defend and enforce our proprietary rights, including our patents. For more information regarding the risks related to our intellectual property, see Item 1.A. 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 one or more partners, 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 product candidates advance through late-stage clinical 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.

ValenzaBio Acquisition

We acquired ValenzaBio, Inc. in an all stock transaction on January 4, 2023. In connection with the Acquisition, we issued an aggregate of 18,888,731 shares of our common stock to ValenzaBio stockholders and assumed options of certain ValenzaBio optionholders which became options for the purchase of an aggregate of 1,249,811 shares of our common stock upon the closing of the Acquisition. The Acquisition added clinical and preclinical development programs to our pipeline, including lonigutamab.

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.

Clinical Trials

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.

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 trial 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 trial 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 trial. The initial PSP must include an outline of the pediatric trial or studies that the sponsor plans to conduct, including trial 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 and enforcement interest to contain healthcare costs, increase transparency in drug pricing, and amend specialty drug pricing practices. For example, in March 2010, the ACA was passed, which substantially changed the way healthcare is financed by both governmental and private insurers. As another example, President Biden signed the Inflation Reduction Act (the IRA) into law on August 16, 2022. The IRA, among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025, directs HHS to negotiate the price of certain single-source drugs and biologics covered under Medicare and imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation.

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, coverage determination is often a time-consuming and costly process. 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.

There can be no assurance that coverage and adequate reimbursement will be obtained from payors. 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. 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 in each such indication as well as other drugs used to treat such patients, such as generic drugs and biosimilars.

We are also developing lonigutamab for the treatment of TED. If approved, lonigutamab would compete with the currently sole approved product, which has achieved wide-spread use in the treatment of TED. There are many other therapies, such as corticosteroids, have been used on an off-label basis to alleviate some of the symptoms of TED.

In addition, we are developing SLRN-517 for the treatment of chronic urticaria. If approved, SLRN-517 would face competition from both existing marketed therapies as well as other symptomatic treatments such as glucocorticosteroids that have been used to alleviate acute exacerbations of chronic urticaria.

Furthermore, there are a number of product candidates in clinical development by third parties that are intended to treat the indications we are pursuing, some of which are late-stage and may receive approvals in the near term.

Employees and Human Capital Resources

As of March 15, 2024, we had 130 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.

Available Information

Our website address is www.acelyrin.com. Information contained on, or that can be accessed through, our website does not constitute part of this Annual Report on Form 10-K. The U.S. Securities and Exchange Commission ("SEC") maintains a website at www.sec.gov that contains reports, proxy and information statements and other information that issuers file or furnish with the SEC electronically. Copies of our annual reports on Form 10-K quarterly reports on Forms 10-Q, current reports on Forms 8-K, and amendments to reports filed or furnished pursuant to Sections 13(a) and 15(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act") may also be obtained electronically, free of charge, on our investor relations website located at investors.acelyrin.com as soon as reasonably practical after we electronically file such material with, or furnish it to, the SEC.

We also use our investor relations website as a channel of distribution for company information, including webcasts of earnings calls and certain events we participate in or host with members of the investor community. We additionally provide information regarding our financial performance, including SEC filings, press and earnings releases, and corporate governance information as part of our investor relations website. The contents of these websites are not intended to be incorporated by reference into any report or other document we file with the SEC.

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. Before deciding to invest in shares of our common stock, you should carefully consider the risks described below, together with the other information contained in this Annual Report on Form 10-K, 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 Annual Report on Form 10-K. 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 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, no products approved for commercial sale, have incurred substantial losses since our inception and anticipate incurring substantial and increasing losses for the foreseeable future.

We are a clinical stage biopharma company with a limited operating history. 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. In addition, we are advancing lonigutamab, an anti-IGF-1R inhibitor, and developing SLRN-517, a monoclonal antibody targeting c-KIT. We have and will continue to incur significant development and other expenses related to our clinical development and ongoing operations. Our net loss for the years ended December 31, 2023, 2022 and 2021 was $381.6 million, $64.8 million and $41.8 million, respectively. As of December 31, 2023, we had an accumulated deficit of $488.7 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 preclinical or clinical trials for our product candidates;
- 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 or any future product candidates;
- seek regulatory approvals for our current or any future product candidates;
- commercialize our current 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 negative macroeconomic trends, such as high rates of inflation, geopolitical instability and war; and
- incur costs associated with operating as a public company.

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 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. 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. For example, despite encouraging results from the open-label Part A of our Phase 2b trial of izokibep in HS, the primary endpoint of HiSCR75 at week 16 did not meet statistical significance in the Part B portion of such trial. This result significantly harmed our stock price and investor perceptions of the prospects for izokibep in HS, extended our development timeline and increased our development costs for such indication. The factors we believe contributed to the Part B results were primarily subject discontinuations unrelated to adverse events and a marked increase in placebo response rates during the course of the trial that led to overall placebo response rates that were markedly higher than historical rates in the HS indication. Our clinical trials are subject to significant risk factors that can have a material and negative impact on outcomes, many of which are beyond our control. Such factors include unexpectedly high placebo response rates and patient responder discontinuations unrelated to adverse events, such as we observed in our Phase 2b trial of izokibep in HS. Other factors that can impact our clinical trial results include, without limitation, patient baseline demographics, clinical protocol adherence, physician and patient scored outcome measures, among others. Any such negative impacts could materially and adversely effect our business, development, regulatory approval and commercialization prospects of izokibep, or other product candidates. In addition, differences in trial design make it difficult to extrapolate the results of earlier clinical trials to later clinical trials. A number of companies in the biopharmaceutical industry, including us, have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unfavorable safety profiles, notwithstanding promising results in earlier trials. In addition, results in one indication may not be predictive of results for the same product candidate in another indication. 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. We may be unable to establish clinical endpoints that applicable regulatory authorities would consider clinically meaningful. 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 submission, the FDA or other regulatory authorities could disagree that we have satisfied their requirements or disagree with our study design, which may require us to complete additional trials, amend our protocols or impose stricter conditions on the commencement of clinical trials. There is typically a high rate of failure of product candidates proceeding through clinical trials, and failure can occur at any time. 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.

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 impose additional requirements before permitting us to initiate a clinical trial, may not authorize us or our investigators to commence or conduct a clinical trial at a prospective trial site, may not allow us to amend trial protocols, or 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 trial sites and CROs, the terms of which can be subject to extensive negotiation and may vary significantly;

- clinical trial sites deviating from trial protocol or dropping out of a trial;
- the number of participants required for clinical trials may be larger, enrollment in clinical trials may be slower or participants may drop out or fail to return for post-treatment follow-up, in each case at a higher rate than we anticipate (as we experienced with respect to participant discontinuations in the Part B portion of our Phase 2b trial of izokibep in HS);
- the cost of clinical trials 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 or support marketing approval;
- reports from clinical testing of other therapies may raise safety, tolerability or efficacy concerns about our product candidates; and
- clinical trials of our product candidates may fail to show appropriate safety, tolerability or efficacy, 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 abandon product development programs.

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 and overall design of the clinical trial, the inability to obtain and maintain participant consents, the ongoing 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. Risks related to patient enrollment are heightened in longer clinical trials. 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 may reduce the number and types of participants available to us. Indication sizes and related disease prevalence may also factor into enrollment. We may experience slower enrollment than anticipated in our trials, which could impact our development timelines, our costs, or other factors. For example, we expect to announce top-line results in our Phase 2b/3 trial in uveitis due to slower enrollment by the end of 2024, versus mid-2024 as initially anticipated.

Participants, including in any control groups, may withdraw from the clinical trial if they are not experiencing improvement in their underlying disease or condition or if they experience other difficulties or issues. Participants may also withdraw from the clinical trial if they experience improvement in their underlying manifestations of disease, and determine that further treatment is not necessary or unduly burdensome relative to their experienced improvement. 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. 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. We have in the past and may in the future experience participant withdrawals or discontinuations from our trials. Such withdrawals may compromise the quality of our data or contribute to negative or inconclusive results from trials, as we experienced in the week 16 Part B results of our Phase 2b trial of izokibep in HS. Any of these conditions may negatively impact our ability to successfully complete such trials and/or include results from such trials in regulatory submissions, which could adversely affect our ability to advance the development of our product candidates in a timely and cost-efficient manner, or at all. For example in light of our week 16 Part B results in our Phase 2b trial of izokibep in HS, the timeline for, and costs associated with, any potential related BLA submission for such indication has been significantly extended.

We could also encounter delays if a clinical trial is suspended, put on clinical hold or terminated by us, IRBs, or regulatory authorities, or if a clinical trial is recommended for suspension or termination by its applicable Data Safety Monitoring Board ("DSMB"). A suspension or termination may be imposed due to a number of factors, including failure to conduct the clinical trial in accordance with applicable regulatory requirements, guidelines or clinical protocols; failure by CROs to perform in accordance with Good Clinical Practice ("GCP") requirements; 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 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 inconclusive 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 conduct preclinical and clinical research in collaboration with other academic, pharmaceutical and biotechnology entities. 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 costs and expenses.

Our development costs will increase if we experience delays or other modifications in clinical testing including, but not limited to, required or desired trial population sizes and/or the number of clinical studies required to be conducted to obtain relevant health authority 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 impact our ability to seek regulatory approval, and/or 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 in, halts to, 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 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, ownership interests will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. 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.

Future clinical trial outcomes could hinder our ability to raise additional capital when needed, or on terms acceptable to us. For example, the failure to achieve the primary endpoint in the Part B week 16 results of the Phase 2b trial of izokibep in HS materially and negatively impacted our stock price. Delays in financings or limited access to capital may impact the scope, timing and ability to conduct all planned clinical development activities, which could materially and adversely affect our business, operations and financial condition.

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 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 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.

Undesirable or clinically unmanageable side effects observed in our clinical trials for our product candidates could occur and cause us or regulatory authorities to interrupt, delay or halt our clinical trials and could result in a more restrictive label or the delay or denial of marketing approval by the FDA or comparable foreign regulatory authorities. We have observed certain adverse events and serious adverse events (“SAEs”) in our clinical trials of izokibep, some of which have been determined to be drug-related by the principal investigator, and/or led to trial discontinuation. 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 adverse events and SAEs. These include, without limitation, injection site reactions, infections such as nasopharyngitis, and inflammatory bowel disease. In addition, candida rates are expected to be observed in 1-3% of trial participants. We expect that additional adverse events and SAEs consistent with known side effects of IL-17A inhibitors may emerge in our ongoing and future clinical trials of izokibep.

If additional adverse events, 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, certain participants have withdrawn from our trials of izokibep in PsA and HS due to SAEs, adverse events such as injection site reactions and erythema, physical relocation and lost to follow up. While we believe that certain side effects could be reversible 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 any of our product candidates 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 adverse events, 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. Adverse events 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 common stock.

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, including HS, 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.

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 and indications. If approved, izokibep would compete with currently approved therapeutics in each such indication as well as other drugs used to treat such patients, such as generic drugs and biosimilars.

We are also developing lonigutamab for the treatment of TED. If approved, lonigutamab would compete with the sole-approved product ("standard of care"), which has achieved wide-spread use in the treatment of TED. In addition to the standard of care, other therapies, such as corticosteroids, have been used on an off-label basis to alleviate some of the symptoms of TED. In addition, we are developing SLRN-517 for the treatment of chronic urticaria. If approved, SLRN-517 would face competition from both existing marketed therapies as well as other symptomatic treatments such as glucocorticosteroids that have been used to alleviate acute exacerbations of chronic urticaria.

Furthermore, there are a number of product candidates in clinical development by third parties that are intended to treat the indications we are pursuing, some of which are late-stage and may receive approvals in the near term.

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, and are approved, 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 (without limitation) 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. 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, coverage determination 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 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 in an indication, 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 a later 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 does not convey any advantage in or shorten the duration of the regulatory review and 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 any or all of our 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 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 impacts of geopolitical instability, public health crises, labor shortages, inflation or other macroeconomic factors impacting our third-party CROs, CMOs, clinical trial sites, investigators or us. 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 with statistical significance in clinical trials, such as what occurred in the week 16 results of the Part B portion of our Phase 2b trial of izokibep in HS.

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 lead to changes in the FDA's review requirements that have been previously communicated to us and our interpretation thereof. Those could include changes to requirements for clinical data or clinical trial design, and 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;
- effectively commercialize any of our products that receive regulatory approval;
- manufacture product in sufficient quantities, and at acceptable quality, timing and 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 rights 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 ongoing and planned clinical trials, even if successfully completed, may not be sufficient for approval of our product candidate for the applicable 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. In certain indications, for example uveitis and TED, our development plan is to conduct a Phase 2b/3 trial, in each case designed to be the first of two registrational trials in the applicable indication. 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. If the FDA does not agree with our planned strategy, the

FDA may ultimately require more Phase 3 clinical trials prior to approval in such indications. 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 trials to show that our product candidate is superior to the new products, such as 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 in the future required to conduct additional Phase 3 clinical trials for uveitis or TED, then our development timeline will be significantly extended, and the related expenses will be significantly increased. Additionally, even if such trials are completed, they may not ultimately be sufficient to achieve health authority approval in one or more indications.

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 our product candidates may, even if approved, be subject to withdrawal procedures by the FDA.

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, participant discontinuation rates, or apparent improvement in trial participants receiving placebo such as those observed in week 16 results of Part B of the Phase 2b trial of izokibep in HS;
- 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, EMA or comparable foreign regulatory authorities will evaluate any combination product designs, review CMOs' manufacturing process and inspect our CMOs' commercial manufacturing facilities and may not approve of such; 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 relative ease of administration of our product candidates, including the potential prevalence and severity of side effects and adverse events, and how such profile compares to those of existing therapies, or those under development;

- the indications for which the products are approved and the approved claims that we may make for the products;
- limitations or warnings contained in the products' FDA-approved labeling, including ones that may be more restrictive than other competitive products;
- distribution and use restrictions imposed by the FDA with respect to such products 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;
- 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;
- 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;
- our ability to offer such product candidates for sale at competitive prices;
- the ability to manage our third-party supply and manufacturing operations effectively and in a cost-effective manner, while increasing production capabilities for our current product candidates to commercial levels;
- the quality and timely supply of our raw material and components from our third -party manufacturers' suppliers;
- 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 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 March 15, 2024, we had 130 full-time employees. As our development and commercialization plans and strategies develop, and as we operate 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 expect to continue to 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 additional deficiencies in our 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 fraud or other illegal activity by our employees, independent contractors, consultants, commercial partners, CROs, CMOs and other parties. 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 any 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, cybersecurity, 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 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. Our ability to realize the anticipated benefits of an acquisition will depend, to a large extent, on our ability to continue the development of assets, technologies and programs we acquire. The expected synergies in development programs, pipelines and other areas of focus 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 assumed in any acquisition.

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 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, 2023, we had federal NOL carryforwards of $92.7 million and state NOL carryforwards of $6.8 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 experienced ownership changes in the past, including in 2023. We completed a Section 382 analysis through December 31, 2023, and concluded that although an ownership change had occurred, the Company's net operating losses and credits were substantially free of limitations as of December 31, 2023. 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, 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, or our data 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 deep fakes, which may be increasingly more difficult to identify as fake, phishing attacks and impersonation of employees), supply chain attacks and vulnerabilities through our third-party service providers, denial-of-service attacks, 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, attacks enhanced or facilitated by AI, 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 have implemented security measures to protect against security incidents, there can be no assurance that these measures will be effective. We take steps designed to detect, mitigate and remediate vulnerabilities in our information systems (such as our hardware and/or software, including that of third parties upon which we rely). We may not, however, be able to detect, mitigate and remediate all such vulnerabilities , including in a timely manner. 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 and patches 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. 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. 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, including individuals, customers, regulators and investors. 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 contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

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, 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, CROs or other vendors 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 or other vendors 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 other health crises, 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 other health crises, including COVID-19, have in the past and could again in the future result in in a disruption of our businesses, delay our research and development programs and timelines, negatively impact productivity and increase risks associated with cybersecurity. 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 wide spread health crisis 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. 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 other health crises may affect their ability to devote sufficient time and resources to our programs. 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.

Our cash and cash equivalents may be exposed to failure of our banking institutions.

We seek to minimize our exposure to third-party losses of our cash and cash equivalents, we hold our balances in multiple financial institutions. Notwithstanding, those institutions are subject to risk of failure. For example, past events surrounding certain banks, including Silicon Valley Bank (“SVB”), First Republic Bank and Signature Bank, created temporary uncertainty on their customers’ cash deposits in excess of Federal Deposit Insurance Corporation limits prior to actions taken by governmental entities. If failures in financial institutions occur where we hold deposits in the future, such events could have a material impact on our cash and cash equivalents balance, expected results of operations or financial performance, and any such loss or limitation on our cash and cash equivalents would adversely affect our business.

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, certain participants in Phase 2 and Phase 3 trials for the sole currently-approved therapy in TED reported developing hearing impairment symptoms. If the public or medical professionals associate these side effects with all IGF-1R therapies, market acceptance of our product candidate lonigutamab, 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 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 common stock.

We previously 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 professionals further contributed to additional material weaknesses in the design and maintenance of: (i) an effective risk assessment process at a precise enough level to identify new and evolving risks of material misstatement in the consolidated financial statements and (ii) 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.

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 annual or interim financial statements will not be prevented or detected on a timely basis.

Through our hiring of necessary personnel and testing of related internal controls for design and operating effectiveness, we have determined that the material weakness related to insufficient accounting personnel was remediated as of December 31, 2023. However, we determined that the other identified material weaknesses, in the design and maintenance of an effective risk assessment process and controls over segregation of duties, remained unremediated as of December 31, 2023. The controls we have implemented, described further below, have not operated for a sufficient period of time and management has not yet concluded, through testing, that such controls are effective.

Such 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.

We have taken and will continue to take certain measures to remediate the material weaknesses described above. We designed and implemented a comprehensive risk assessment process to identify and design our control activities and we continue to assess risks on a continuous basis to timely identify new exposures or risk categories as business practices change. We also designed and implemented preventive and detective controls over the segregation of duties related to journal entries and account reconciliations. Specifically, we restricted the ability for one individual to both (i) create and post a journal entry in the general ledger and (ii) prepare and review account reconciliations. While we believe these measures will remediate the material weaknesses identified and strengthen our internal control over financial reporting, the material weaknesses will not be considered remediated until the controls described above 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, 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 continue to 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 common stock could be negatively affected. As a result, we could also become subject to investigations by the Nasdaq Global Select 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. 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 licensor and collaborators related to izokibep, lonigutamab, and SLRN-517, we do not own any issued patents. 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 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, including, without limitation, Australia, India, New Zealand and Singapore, 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 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 other current or 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, licensors such as Affibody or Pierre Fabre 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;
- 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 pandemics or health crises arise, 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 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 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 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. For example, we depend on our license and collaboration agreement with Affibody for the development of izokibep, which grants us an exclusive license to develop izokibep worldwide, subject to certain rights granted by Affibody to Inmagene under the Inmagene Agreement with respect to the development, commercialization and manufacturing of izokibep in certain Asian countries. Affibody has retained rights under the license and collaboration agreement to the extent necessary to carry out its obligations for manufacturing under the Inmagene Agreement. It is difficult to monitor whether Affibody or Inmagene, or any of our other licensors limit their use of the product candidates to these permitted 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 may at times choose to collaborate with academic institutions to accelerate our preclinical research or development. While we do not currently engage, and 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. Although none of our licenses to date are subject to march-in rights, 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 2032, with the exception of a temporary suspension from May 1, 2020 through March 31, 2021, unless additional Congressional action is taken.

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 take effect progressively starting in fiscal year 2023, although the Medicare drug price negotiation program is currently subject to legal challenges. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. HHS released a report in February 2023 outlining three new models for testing by the CMS Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. Further, in December 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. The National Institute of Standards and Technology thereafter published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework. 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 and rules, contractual obligations, industry standards, policies, and other obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation (including class claims); 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 or our vendors 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 laws and regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements, and other obligations.

Various legislative and regulatory bodies, or self-regulatory organizations, may enact new or expand or otherwise revise existing laws, rules or regulations, 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, in the past few years, numerous U.S. states—including California, Virginia, Colorado, Connecticut, and Utah—have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. As applicable, such rights may include the right to access, correct, or delete certain personal data, and to opt-out of certain data processing activities, such as targeted advertising, profiling, and automated decision-making. The exercise of these rights may impact our business and ability to provide our products and services. Certain states also impose stricter requirements for processing certain personal data, including sensitive information, such as conducting data privacy impact assessments. These state laws allow for statutory fines for noncompliance. For example, the California Consumer Privacy Act, as amended by the California Privacy Rights Act of 2020 (“CPRA") (collectively, “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 CCPA and other comprehensive state privacy laws include limited exceptions, including for certain information collected as part of clinical trials, these developments may impact our processing of personal information and increases the compliance costs and legal risk for us and the third parties upon whom we rely. Similar laws are being considered in several other states, as well as at the federal and local levels and we expect more states to pass similar laws in the future. 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 clinical trial activities 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 GDPR imposes 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 GDPR also provides 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 standard contractual clauses, the UK's International Data Transfer Agreement / Addendum, and the EU-U.S. Data Privacy Framework and the UK extension thereto (which allows for transfers to relevant U.S.-based organizations who self-certify compliance and participate in the Framework), 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 CCPA and 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 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 and result in adverse consequences including but not limited to: government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-action claims) and mass arbitration demands; additional reporting requirements and/or oversight; bans on processing personal data; orders to destroy or not use personal data; and imprisonment of company officials. In particular, plaintiffs have become increasingly more active in bringing privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations. 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 also publicly post policies concerning our collection, use, disclosure and other processing of the personal information provided to us by our website visitors and certain other parties. 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 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 individuals and entities to lose trust in us, any of which could adversely affect our business, financial condition, results of operations and prospects.

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, Pierre Fabre and Novelty Nobility, 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. For example, in November 2023 we reported a third party programming error impacted dose sequencing in our Phase 2b/3 trial of izokibep in PsA. In addition, 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. For example, although the third party programming error impacting dose sequencing in the Phase 2b/3 trial in PsA has been corrected, remediation efforts are needed and the ultimate determination if such trial could be part of a registrational package is subject to regulatory agency review. 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 to manufacture bulk drug substances, drug products, raw materials, samples, device 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, clinical and commercial 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.

Furthermore, there are a limited number of suppliers for device components, raw materials, and packaging we use in our product candidates, which exposes us to the risk of disruption in the supply of the materials necessary to manufacture our product candidates for our preclinical studies and clinical trials, and if approved, ultimately for commercial sale.

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 have entered 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 and lonigutamab 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. For example, we were recently notified that manufacturing facilities where our CMO manufactures lonigutamab drug substance will be closing. Accordingly, we are in the process of transferring lonigutamab drug substance manufacturing to the CMO's alternative manufacturing plant, which will require process changes, comparability studies, and regulatory filings to compliantly support clinical trials. Such tech transfer activities involves rigorous planning and execution with associated technical resources. We cannot assure you that we will not experience any disruptions in our lonigutamab drug substance supply as a result of the transfer. In this regard, although we have not experienced any significant disruption as a result of our reliance on limited or sole source suppliers to date, 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, potential disruptions due to the ongoing COVID-19 pandemic or other pandemics or health crises;
- 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 other pandemics or health crises, 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 scale-up the manufacturing process and produce qualification lots for our product candidates with 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 and testing 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 Ownership of Our Common Stock

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 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 ongoing and future preclinical studies and clinical trials, or the addition or termination thereof;
- 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;
- fluctuations in stock-based compensation expense;
- the continuing impact of negative macroeconomic trends, such as high rates of inflation, supply chain disruptions and geopolitical instability, and the COVID-19 pandemic 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 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 is likely to continue to be volatile, which could result in substantial losses for investors.

The market price of our common stock is likely to continue 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;

• announcements relating to our product candidates, including the results of clinical trials by us or our collaborators such as our announcement of week 16 results from the Part B portion of our Phase 2b trial of izokibep in HS and the third party dose sequencing programming error in our Phase 2b/3 trial in PsA, both of which significantly harmed our stock price;

• 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 financing efforts and receipt, or lack of receipt, of funding in support of conducting our business;

• sales of our common stock by us, our insiders, or other stockholders, or issuances by us of shares of our common stock in connection with strategic transactions, financings or otherwise;

• 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, including the pending purported securities class action lawsuit against us;

• public health crises, natural disasters, 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 common stock, regardless of our actual operating performance.

We are an “emerging growth company” and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our 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 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.

We could be an emerging growth company for up to five years following the completion of our May 2023 initial public 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 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 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, to the fullest extent permitted by law, provides 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 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 public 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, and/or 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. That may discourage lawsuits against us and our directors, officers, other employees or agents.

Our board of directors are authorized to issue and designate shares of our preferred stock without stockholder approval.

Our amended and restated certificate of incorporation authorizes our board of directors, without the approval of our stockholders, to issue shares of preferred stock, subject to limitations prescribed therein or by applicable law, rules and regulations; to establish the number of shares to be included in each such series of preferred stock; and to fix the designation, powers, preferences and rights of each such series and the qualifications, limitations or restrictions thereof. The powers, preferences and rights of these additional series of convertible preferred stock may be senior to or on parity with our common stock, which may reduce our 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 our stockholders' 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 common stock, which may never occur, will be our stockholders' sole source of gain on 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 or the state of war between Israel and Hamas and the related risk of a larger regional 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 common stock is 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 analysts cease coverage of us, we could lose visibility in the financial markets, and the trading price for our 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 incur increased costs as a result of operating as a public company, and our management is required to devote substantial time to new compliance initiatives and corporate governance practices.

As a public company we 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 Select 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 continue to 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 over those incurred as a private company and to make some activities more time consuming and costly, particularly after we are no longer an emerging growth company. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements, and these increased costs may require us to reduce costs in other areas of our business. 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.

Failure to 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 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. However, we are required to comply with the SEC's rules implementing Sections 302 and 404 of the Sarbanes-Oxley Act, which require our management 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. Our first annual assessment of our internal control over financial reporting will not be required until our second annual report on Form 10-K, though we are required to disclose changes made in our internal control over financial reporting on a quarterly basis. Moreover, 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.

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, as of December 31, 2023, material weaknesses exist in the design and operating effectiveness of our internal control over financial reporting. If we are unable to remediate these material weaknesses, or we identify more material weaknesses that we are not able to timely remediate to meet the applicable compliance deadline for the disclosure and attestation requirements of Section 404 of the Sarbanes-Oxley Act, investors may lose confidence in the accuracy and completeness of our financial reports. As a result, the market

price of our common stock could be negatively affected and we could become subject to investigations by the stock exchange on which our securities are listed, the SEC or other regulatory authorities, which could require additional financial and management resources. In addition, if we fail to remedy any material weakness, our financial statements could be inaccurate, and we could face restricted access to capital markets.

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

We are subject to the periodic reporting requirements of the Exchange Act. We designed our disclosure controls and procedures to provide reasonable assurance that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. Our disclosure controls and procedures may not be effective. 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 because of the inherent limitations in all control systems. For example, our principal executive officer and principal financial officer concluded that, as of December 31, 2023, our disclosure controls and procedures were not effective due to material weaknesses in our internal control over financial reporting that have not been remediated as of December 31, 2023.

In any event, 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 have been named a defendant in a purported securities class action lawsuit. This could result in substantial damages or other expenses, and could divert management's time and attention from our business.

The market price of our common stock is likely to continue to be volatile. In the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. In addition, litigation, including securities class action litigation, has often followed the announcement of adverse clinical or regulatory events such as negative or inconclusive clinical trial results, announcements of significant business transactions, such as the sale or purchase of a company, or announcement of any other strategic transaction. Any of these events may also result in investigations by the SEC or other regulatory authorities. In this regard, on November 15, 2023, a purported federal securities class action lawsuit was commenced in the United States District Court for the Central District of California. An amended complaint was filed on March 26, 2024, naming us and current and former officers and directors as defendants. The complaint alleges that the defendants violated the Exchange Act and Securities Act in its disclosures regarding our Phase 2b trial of izokibep in HS. The complaint seeks damages and an award of reasonable costs and expenses, as well as such other and further relief as the court may deem just and proper. This lawsuit is subject to inherent uncertainties, including its outcome. We could be subject to additional litigation in the future. We could be forced to expend significant resources and incur substantial legal fees and costs in the defense of this suit, and we may not prevail. We have not established any reserve for any potential liability relating to this lawsuit. It is possible that we could, in the future, incur judgments or enter into settlements of claims for monetary damages. A decision adverse to our interests could result in the payment of substantial damages, or possibly fines, and could have a material adverse effect on our cash flow, results of operations and financial position.

Item 1B. Unresolved Staff Comments

None

Item 1C. Cybersecurity

Risk management and strategy

We have implemented and maintain various information security processes designed to identify, assess and manage material risks from cybersecurity threats to our critical computer networks, third party hosted services, communications

systems, hardware and software, and our critical data, including intellectual property, data related to our clinical trials and other confidential information that is proprietary, strategic or competitive in nature (“Information Systems and Data”).

Our information security function, which is led by our IT department, helps to identify, assess and manage the Company’s cybersecurity threats and risks. Our IT team identifies and assesses risks from cybersecurity threats by monitoring and evaluating our threat environment and the Company’s risk profile using various methods including, for example, manual and automated tools, analyzing reports of threats and threat actors, conducting internal and external scans of our environment, periodic penetration tests conducted by third parties, utilization of a 24x7 security operations center (SOC) that provides monitoring and alert services, evaluating threats reported to us, and coordinating cross-functionally, with Company management and externally (e.g., with law enforcement) concerning threats.

Depending on the environment, we implement and maintain various technical, physical, and organizational measures, processes, standards and policies designed to manage and mitigate material risks from cybersecurity threats to our Information Systems and Data, including, for example: a Cybersecurity Incident Response Policy; various other policies, plans, and frameworks in regards to (without limitations) access, acceptable use, password security and software system development; physical and administrative access and network security controls; data segregation; encryption of certain data; leveraging of certain SOC II-certified vendors; management, tracking and disposal of certain assets; systems monitoring; participating in information sharing and analysis centers (ISACs) to share and receive threat intelligence specifically related to biopharma and healthcare companies; and maintaining cyber insurance.

Our assessment and management of material risks from cybersecurity threats are integrated into the Company’s overall risk management processes. The Company has an IT Steering Committee made up of cross-disciplinary senior management, including (among others) the Chief Legal and Administrative Officer, Chief Financial Officer and Chief Operating Officer, along with IT leadership and representatives from several additional departments. For example, the IT department works with the IT Steering Committee and other senior management personnel to prioritize certain risk management processes and mitigate cybersecurity threats that are more likely to lead to a material impact to our business.

We use third-party service providers to assist us from time to time to identify, assess, and manage material risks from cybersecurity threats, including for example, outside consultants, third party penetration testing providers, and threat intelligence and forensic providers.

We use third-party service providers to perform a variety of functions throughout our business, such as email and hosting providers, contract research organizations (CROs) and contract manufacturing organizations (CMOs). We have certain vendor management processes that we may use as appropriate to manage cybersecurity risks associated with our use of these providers. These processes may include the imposition of information security contractual obligations on vendors, as well as quality control elements for certain vendors. Depending on the nature of the services provided, the sensitivity of the information systems and data at issue, and the identity of the provider, our vendor management processes may involve different levels of assessment designed to help identify cybersecurity risks associated with a provider and impose contractual obligations related to cybersecurity on the provider.

For a description of the risks from cybersecurity threats that may materially affect the Company and how they may do so, see our risk factors under Part 1. Item 1A. Risk Factors in this Annual Report on Form 10-K, including "If our internal information technology systems, or those used by our CROs, CMOs, clinical sites or other contractors or consultants upon which we rely, or our data 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."

Governance

Our board of directors addresses the Company’s cybersecurity risk management as part of its general oversight function. The board of directors' audit committee is responsible for overseeing the Company’s cybersecurity risk management processes, including oversight and mitigation of risks from cybersecurity threats.

Our cybersecurity risk assessment and management processes are implemented and maintained by certain Company management, led by our Executive Director of IT & Cybersecurity, who has over 20 years' of work experience in IT and cybersecurity.

The Executive Director of IT & Cybersecurity is responsible for hiring appropriate personnel, helping to integrate cybersecurity risk considerations into the Company’s overall risk management strategy, and communicating key priorities to relevant personnel. The Executive Director of IT & Cybersecurity, together with certain other senior management personnel, is responsible for approving functional budgets, implementing approved, phase-appropriate policies, plans and

guidelines, helping prepare for potential cybersecurity incidents, reviewing security assessments and other security-related reports and overseeing cybersecurity processes.

Our Cybersecurity Incident Response Policy is designed to escalate certain cybersecurity incidents to members of senior management depending on the circumstances, including our Disclosure Committee, as appropriate. Senior management works with the Company's cybersecurity incident management team to help the Company mitigate and remediate notified cybersecurity incidents, comply with applicable laws, regulations and contractual provisions and engage advisors as appropriate. In addition, such policy includes reporting to the audit committee of the board of directors for certain cybersecurity incidents.

The audit committee receives periodic reports from the Executive Director of IT & Cybersecurity concerning the Company's significant cybersecurity threats and risk and the processes the Company has implemented to address them. The audit committee also has access to advisors, and various other reports, and presentation materials related to cybersecurity threats, risk and mitigation.

Item 2. Properties

Our principal executive office is located at 4149 Liberty Canyon Road, Agoura Hills, California where we lease 10,012 square feet of office space. Our lease expires in August 2028. In July 2023, the Company entered into a lease agreement to rent approximately 22,365 square feet of office space in South San Francisco with the commencement date to be determined upon completion of work to be performed by the landlord. The term of the lease is 60 months with an option to extend it for an additional three years at then current market rates. The lease has not commenced as of December 31 2023. We believe our facilities are adequate for our current needs and that suitable additional or substitute space would be available if needed.

Item 3. Legal Proceedings

On November 15, 2023, a purported federal securities class action lawsuit was commenced in the United States District Court for the Central District of California. An amended complaint was filed on March 26, 2024 (Boukadoum v. Acelyrin, Inc. et al., No. 2:23-cv-09672-FMO-MAA), naming us and current and former executive officers and directors as defendants. The complaint alleges that the defendants violated the Exchange Act and Securities Act by misleading investors about the Phase 2b trial of izokibep in HS. The original complaint was filed following our announcement of the week 16 results from the Part B portion of such Phase 2b trial. The complaint seeks damages and an award of reasonable costs and expenses, including attorneys' fees, expert fees and other costs, as well as such other and further relief as the court may deem just and proper. It is possible that additional suits will be filed, or allegations made by stockholders, with respect to these same or other matters and also naming us and/or our officers and directors as defendants. This lawsuit and any other potential lawsuits are subject to inherent uncertainties, and the actual defense and disposition costs will depend upon many unknown factors. We could be forced to expend significant resources in the defense against this and any other related lawsuits and we may not prevail.

From time to time, we may become involved in additional legal proceedings or be subject to claims arising in the ordinary course of our business. Regardless of outcome, such additional proceedings or claims could 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.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information for Common Stock

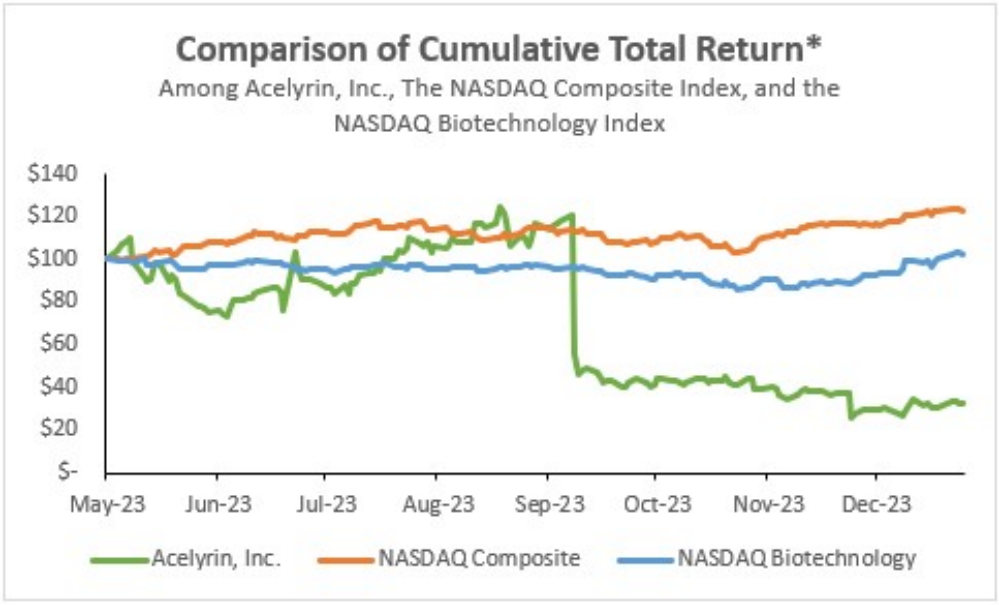
Our common stock has traded on the Nasdaq Global Market under the symbol “SLRN” since May 5, 2023. Prior to that, there was no public market for our common stock.

Dividend Policy

We have never declared or paid, and do not anticipate declaring or paying in the foreseeable future, any cash dividends on our capital stock. Any future determination as to 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.

Stock Price Performance Graph

The following stock performance graph illustrates a comparison from May 5, 2023 (the date our common stock commenced trading on the Nasdaq Global Select Market) through December 31, 2023, of the total cumulative stockholder return on our common stock, the Nasdaq Composite Index and the Nasdaq Biotechnology Index. The graph assumes an initial investment of $100 on May 5, 2023 at the opening trading price of $18.00 per share, and that all dividends were reinvested, although dividends have not been declared on our common stock. The comparisons in the graph are required by the SEC and are not intended to forecast or be indicative of possible future performance of our common stock.



*$100 invested on 5/5/23 (first trading day of SLRN) in stock or index. Fiscal year ending December 31.

The above Stock Performance Graph and related information shall not be deemed “soliciting material” or to be “filed” with the Securities and Exchange Commission nor shall such information be incorporated by reference into any

future filing under the Securities Act or the Exchange Act, each as amended, except to the extent that we specifically incorporate it by reference into such filing.

Stockholders

As of March 15, 2024, there were 29 registered stockholders of record for our common stock. This number of registered stockholders does not include stockholders whose shares are held in street names by brokers and other nominees, or may be held in trust by other entities. Therefore, the actual number of stockholders is greater than this number of registered stockholders of record.

Unregistered Sales of Equity Securities

None

Use of Proceeds from Initial Public Offering of Common Stock

On May 4, 2023, our Registration Statement on Form S-1 (File No. 333-271244) was declared effective by the SEC for our IPO. At the closing of the IPO on May 9, 2023, we sold 34,500,000 shares of common stock, which included the exercise in full by the underwriters of their option to purchase 4,500,000 additional shares, at an initial public offering price of $18.00 per share and received gross proceeds of $621.0 million, which resulted in net proceeds to us of approximately $573.6 million, after deducting underwriting discounts and commissions and other offering costs totaling approximately $47.4 million. None of the expenses associated with the IPO were paid to directors, officers, persons owning ten percent or more of any class of equity securities, or to their associates, or to our affiliates, other than payments from our net proceeds in the ordinary course of business to officers for salaries and to non-employee directors as compensation for service on the board of directors or committees of the board of directors. Morgan Stanley & Co. LLC, Jefferies LLC, Cowen and Company, LLC and Piper Sandler & Co. acted as joint book-running managers for the IPO.

The net proceeds from our IPO have been invested according to our approved investment policy in a mix of money market funds and high-quality, fixed income securities. There has been no material change in the planned use of IPO proceeds from that described in the final prospectus filed with the SEC on May 5, 2023 pursuant to Rule 424(b)(4).

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None

Item 6. [RESERVED]

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and related notes and other financial information included in Part II, Item 8 of this Annual Report. Some of the information contained in this discussion and analysis and other parts of this Annual Report on Form 10-K contain forward-looking statements based upon current beliefs, plans and expectations related to future events and our future financial performance that involve risks, uncertainties and assumptions, such as statements regarding our intentions, plans, objectives and expectations for our business. Our actual results and the timing of selected events could differ materially from those described in or implied by these forward-looking statements as a result of several factors, including those set forth under "Risk Factors" in Part I, Item 1A of this Annual Report on Form 10-K.

This discussion and analysis generally addresses 2023 and 2022 items and year-over-year comparisons between 2023 and 2022. Discussions of 2021 items and year-over-year comparisons between 2022 and 2021 that are not included in this Annual Report can be found in "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our final prospectus filed with the SEC on May 5, 2023 pursuant to Rule 424(b)(4).

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 may 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 plan to utilize the results from initial clinical trials and the learnings we obtain from emerging biology to potentially expand the application of our candidates to other indications in which there are significant unmet needs.

Our current portfolio consists of multiple clinical-stage product candidates being investigated across several indications.

Our lead product candidate, izokibep, is being evaluated in multiple immunologic indications, including hidradenitis suppurativa (HS), psoriatic arthritis (PsA), and uveitis. We are also developing lonigutamab for the treatment of thyroid eye disease ("TED"), as well as are developing SLRN-517 in 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, conducting clinical trials, 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 increasing 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.

We have incurred significant losses and negative cash flows from operations since our inception. Our net loss for the years ended December 31, 2023 and 2022 was $381.6 million and $64.8 million, respectively. The net loss of $381.6 million in the year ended December 31, 2023 includes $123.1 million of expenses related to acquired in-process research and development assets without alternative future use, $47.3 million in stock-based compensation, and $10.0 million license fee payment to Pierre Fabre incurred in connection with the ValenzaBio acquisition. As of December 31, 2023, we had an accumulated deficit of $488.7 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. We anticipate that our expenses will increase significantly in connection with our ongoing activities. For example, in 2024, we have significant manufacturing activities to support BLA readiness for izokibep at our contract manufacturers including scale-up, product qualification lots, and stability studies. As a result, we expect the manufacturing spend portion of our research and development expenses in 2024 to be significantly higher than other years prior to potential product launch. 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. In addition, we may seek additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. 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.

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.

As of December 31, 2023, we had $721.3 million in cash, cash equivalents and short-term marketable securities. On May 9, 2023, we closed our initial public offering (“IPO”) in which we sold an aggregate of 34,500,000 shares of common stock at a price to the public of $18.00 per share, which included 4,500,000 shares issued upon the full exercise by the underwriters of their option to purchase additional shares of common stock. We received aggregate net proceeds from the IPO of approximately $573.6 million, after deducting underwriting discounts and commissions and other offering costs. Based on our current operating plan, we estimate that our existing cash and cash equivalents and short-term marketable securities will be sufficient to fund our operating plan and capital expenditure requirements for at least the next 12 months from the date of this Annual Report on Form 10-K. 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.

Macroeconomic Trends

We continue to actively monitor the impact of various macroeconomic trends, such as the military conflicts in Ukraine and the Middle East, high rates of inflation, supply chain disruptions and geopolitical instability 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. Our business has been, and may continue to be, impacted by the negative macroeconomic trends wherever we have clinical trial sites, contract manufacturing organization facilities or other business operations. For example, the COVID-19 pandemic has caused disruption in the operations of CMOs, CROs, and other third parties upon whom we rely.

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 our 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.

ValenzaBio Acquisition

On December 20, 2022, we entered into the ValenzaBio Merger Agreement to acquire outstanding equity of ValenzaBio (the "Acquisition"). 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 SLRN-517. We determined that the Acquisition should be accounted for as an asset acquisition after considering whether substantially all of the fair value of the gross assets acquired was concentrated in a single asset or group of assets and whether we acquired a substantive process capable of significantly contributing to our ability to create outputs. As consideration, at the closing, we (i) issued 18,885,731 shares of our common stock to ValenzaBio stockholders and paid $7,663 in cash to one non-accredited investor, and (ii) assumed options of ValenzaBio optionholders who entered into consulting agreements with us, which became options for the purchase of an aggregate of 1,249,811 shares of our common stock upon the closing of the Acquisition on January 4, 2023. Outstanding shares and options were exchanged at an exchange ratio of 0.8027010-for-one. The assumed options vested on March 31, 2023 and are exercisable until the earlier of (i) 12 months following the termination of the option holder’s continuous service with us, or (ii) the original expiration date of such assumed option.

License and Collaboration Agreements

Affibody License and Collaboration Agreement

On August 9, 2021, we entered into a license and collaboration 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 doing so, 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.

Pierre Fabre Agreement

Upon the closing of the Acquisition, we became the successor to ValenzaBio's rights under the March 25, 2021 license and commercialization agreement between ValenzaBio and Pierre Fabre, as amended (the "Pierre Fabre Agreement"). 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. The 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 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.

Novelty Nobility License and Commercialization Agreement

On January 4, 2023, in connection with the acquisition of ValenzaBio, we 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 SLRN-517, an unmodified IgG1 monoclonal antibody, as a therapeutic treatment.

For further detail on our license and collaboration agreements, see Note 7 to our consolidated financial statements entitled "Significant Agreements" in this Annual Report on Form 10-K.

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. Substantially all of our third-party expenses relate to the development of izokibep, lonigutamab, SLRN-517 and other programs. 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 and/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;
- 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.

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. For example, in September 2023, we announced that the primary endpoint of HiSCR75 at week 16 did not meet statistical significance in Part B of the Phase 2b trial of izokibep in HS. The factors we believe contributed to the Part B results, including subject discontinuations unrelated to adverse events and a marked increase in placebo response rates during the course of the trial, could negatively impact the results of ongoing and future clinical trials of izokibep, including the ongoing Phase 3 trial of izokibep in HS or trials in other indications. In any event, the negative results in Part B of the Phase 2b trial significantly extended our development timeline and significantly increased our development costs for HS. In this regard, we had previously planned for the inclusion of the Part B results from our Phase 2b trial of izokibep in HS as part of the planned registrational package for HS. However, we now would need to conduct and successfully complete both our ongoing Phase 3 trial in HS, as well as an additional Phase 3 trial in HS, for any registrational package in such indication.

General and Administrative

Our general and administrative expenses consist primarily of personnel-related costs, legal and external 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. We also expect an increase in general and administrative expenses associated with being a public company, including costs related to accounting, audit, legal, regulatory, and tax-related services associated with maintaining compliance with applicable Nasdaq and SEC requirements, as well as costs related to the filed purported securities class action lawsuit against us; additional director and officer insurance costs; and investor and public relations costs.

Other Income (Expense), Net

Other income (expense), net consists primarily of interest income and amortization of premiums and accretion of discounts on short-term marketable securities, net foreign currency transaction loss and gain on remeasurement of derivative tranche liability.

Results of Operations

Comparison of the Years Ended December 31, 2023 and 2022

The following table summarizes our results of operations for the years ended December 31, 2023 and 2022 (dollars in thousands):

	Year Ended December 31,		Change	
	2023	2022	$	%
Operating expenses:				
Research and development	$ 355,886	$ 55,632	$ 300,254	540 %
General and administrative	66,178	13,547	52,631	389 %
Total operating expenses	422,064	69,179	352,885	510 %
Loss from operations	(422,064)	(69,179)	(352,885)	510 %
Change in fair value of derivative tranche liability	10,291	487	9,804	2013 %
Interest income	30,555	4,052	26,503	654 %
Other expense, net	(423)	(132)	(291)	220 %
Net loss	$ (381,641)	$ (64,772)	$ (316,869)	489 %

* not meaningful

Research and Development Expenses

The following table summarizes our research and development expenses for the years ended December 31, 2023 and 2022 (dollars in thousands):

	Year Ended December 31,		Change	
	2023	2022	$	%
External costs:				
License fees and acquired in-process research and development expenses	$ 148,437	$ —	$ 148,437	100 %
CRO, CMC, transition services	159,794	43,061	116,733	271 %
Professional consulting services	10,850	1,890	8,960	474 %
Other research and development costs, including laboratory materials and supplies	264	44	220	500 %
Internal costs:				
Personnel-related costs	35,200	10,278	24,922	242 %
Facilities and overhead costs	1,341	359	982	274 %
Total research and development expense:	355,886	55,632	300,254	540 %

Research and development expenses increased by $300.3 million, from $55.6 million for the year ended December 31, 2022, to $355.9 million for the year ended December 31, 2023. The increase was primarily related to license fees and acquired in-process research and development expenses, external CRO, CMO and Affibody transition services expenses and costs related to personnel and professional consulting services.

License fees and acquired in-process research and development expenses include $123.1 million related to the acquired lonigutamab and SLRN-517 assets, and $10.0 million related to a non-refundable license fee paid in connection with the amendment of Pierre Fabre Agreement, incurred in connection with the Acquisition. The estimated fair value of lonigutamab asset of $114.8 million and SLRN-517 asset of $8.2 million, were expensed as we concluded that these assets were still in clinical and preclinical development and have no alternative future use. During the year ended December 31, 2023, we have paid Affibody $15.0 million upon achievement of the first development milestone for izokibep under the Affibody Agreement.

External CRO, CMO and Affibody transition services expenses increased by $116.7 million, from $43.1 million for the year ended December 31, 2022 to $159.8 million for the year ended December 31, 2023. We incurred development expenses of $0.2 million and $18.2 million under our Affibody transition services agreement for the years ended December 31, 2023 and 2022, respectively. We expect that our CRO and CMO expenses related to our products in development will continue to increase as we progress in the clinical trials of these assets.

Our CRO and CMO expenses by program for the years ended December 31, 2023 and 2022 were as follows (in thousands):

	Year ended December 31,	
	2023	2022
Izokibep	$ 138,438	$ 24,816
Lonigutamab (XLRN-421)	11,385	—
SLRN-517	7,306	—
Other	2,442	—
Total CRO, CMC, transition services	$ 159,571	$ 24,816

Expenses related to professional consulting services increased by $9.0 million, from $1.9 million for the year ended December 31, 2022 to $10.9 million for the year ended December 31, 2023. We recognized stock-based compensation expense of $3.1 million and consulting services expense of $0.7 million for the year ended December 31, 2023. These expenses relate to the assumed ValenzaBio options and expenses incurred for former ValenzaBio research and development employees, who entered into consulting agreements with us. Other professional consulting services expenses increased by $5.1 million, as we engage with other consultants for our research and development activities.

Personnel-related costs increased by $24.9 million from $10.3 million for the year ended December 31, 2022 to $35.2 million for the year ended December 31, 2023. In January 2023, we recognized $2.5 million severance obligation expense in connection with the Acquisition. Employees' salaries and benefits increased by $14.2 million for the year ended December 31, 2023 compared to the year ended December 31, 2022 related to increased research and development headcount from 33 to 93 employees. Stock-based compensation expense increased by $8.2 million, from $1.4 million for the year ended December 31, 2022 to $9.6 million for the year ended December 31, 2023, as a result of grants of additional options, restricted stock units and performance-based restricted stock units granted during the year ended December 31, 2023 as well as due to an increase in our common stock fair value.

Facilities and allocated overhead costs increased by $1.0 million from $0.4 million for the year ended December 31, 2022 to $1.3 million for the year ended December 31, 2023, primarily as a result of entering into a short-term office lease in September 2023, increased allocated expenses, maintenance agreements expenses, software subscriptions and other IT related expenses.

General and Administrative Expenses

General and administrative expenses increased by $52.6 million from $13.5 million for the year ended December 31, 2022 to $66.2 million for the year ended December 31, 2023.

Employees' salaries and benefits increased by $39.3 million for the year ended December 31, 2023 compared to December 31, 2022 as a result of increase in headcount from 14 to 42 employees as well as $0.6 million severance expense related to the departure of the former Chief Financial Officer ("CFO") in August 2023. The stock-based compensation expense increased by $32.0 million from $2.7 million for the year ended December 31, 2022 to $34.7 million for the year ended December 31, 2023. For the year ended December 31, 2023, we recognized $5.5 million related to restricted stock unit awards granted to our chief executive officer that vested upon the IPO closing. For the year ended December 31, 2022 we recognized $1.3 million expense related to vested restricted stock awards granted to our chief executive officer which vested in March 2022. In January 2023, in connection with the Acquisition, we recognized $2.7 million stock-based compensation expenses. We recognized $4.4 million of stock-based compensation in August 2023 in connection with the departure of the former CFO. The remaining increase in our stock-based compensation expense of $19.4 million was due to additional stock options, restricted stock units and performance-based restricted stock units granted and increase in our common stock fair value. In January 2023, in connection with the Acquisition, we also recognized $2.4 million severance obligation expense. Expenses related to professional consulting services increased by $10.0 million, from $3.3 million for the year ended December 31, 2022 to $13.3 million for the year ended December 31, 2023 due to an increase in consulting, legal, recruiting, audit and accounting services to support our Company's growth and being a public company. Facilities

and allocated overhead costs increased by $2.3 million from $0.3 million for the year ended December 31, 2022 to $2.6 million for the year ended December 31, 2023, primarily as a result of increased allocated expenses, bank fees, rent, including new short-term lease, insurance expenses, software subscriptions and other IT related expenses. Other miscellaneous general and administrative expenses increased by $1.1 million during the year ended December 31, 2023 as compared to the year ended December 31, 2022, mainly due to an expense related to share settlement of ValenzaBio board members' options in connection with the Acquisition.

Total Other Income (Expense), Net

Total other income, net increased by $36.0 million, from $4.4 million net income for the year ended December 31, 2022 to $40.4 million net income for the year ended December 31, 2023. The increase was primarily related to interest income earned on our available-for-sale marketable securities and the change in fair value of the Series C derivative tranche liability.

We recognized $30.6 million and $4.1 million interest income earned on our available-for-sale marketable securities for the years ended December 31, 2023 and 2022, respectively.

We recognized a gain of $10.3 million related to the change in fair value of the Series C derivative tranche liability for the year ended December 31, 2023. The Series C derivative tranche liability was recognized in September 2022 and represents an obligation to issue Series C redeemable convertible preferred stock shares in the Series C second tranche closing under certain conditions. The Series C derivative tranche liability was recorded at fair value and remeasured at each reporting period until it was terminated upon the IPO closing in May 2023.

We recognized $0.4 million and $0.1 million of Other expense, net that related to transactions in foreign currencies for the years ended December 31, 2023 and 2022, respectively.

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 and issuance of our common stock upon the IPO closing in May 2023.

As of December 31, 2023, we had $721.3 million in cash and cash equivalents and short-term marketable securities. Based on our current operating plan, we estimate that our existing cash and cash equivalents and short-term marketable securities will be sufficient to fund our current operating plan and capital expenditure requirements for at least the next 12 months from the date of this Annual Report on Form 10-K. 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 (and/or as a result of negative of inconclusive clinical trial results for any of our product candidates) 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 as well as scale up 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;
- expenses and liabilities associated with the pending purported class action securities lawsuit;
- the costs associated with being a public company; and
- the impacts of negative macroeconomic trends, such as high rates of inflation, global supply chain disruptions and geopolitical instability, 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. In addition, we may seek additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. 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,	
	2023	2022
Net cash used in operating activities	$ (169,705)	$ (61,520)
Net cash used in investing activities	(447,744)	(47,874)
Net cash provided by financing activities	568,436	274,262
Net increase (decrease) in cash and cash equivalents	$ (49,013)	$ 164,868

Operating Activities

Net cash used in operating activities was $169.7 million and $61.5 million for the years ended December 31, 2023 and 2022, respectively.

Cash used in operating activities in the year ended December 31, 2023 was primarily due to our net loss for the period of $381.6 million, of which $10.0 million is presented as cash used in investing activities as it related to a license fee payment to Pierre Fabre incurred in connection with the Acquisition. Adjustments to net loss for non-cash items also included $123.1 million expense related to in-process research and development assets without alternative future use incurred in connection with the Acquisition, $47.3 million related to stock-based compensation expense, $10.5 million gain related to an accretion of discounts on short-term marketable securities, $10.3 million gain related to the change in fair value of the derivative tranche liability, $0.2 non-cash lease expense and $0.1 million depreciation and amortization expense. The changes in operating assets and liabilities of $52.1 million include an increase of $34.4 million in accounts payable, an increase of $24.9 million in accrued research and development expenses, an increase of $1.7 million in accrued compensation and other current liabilities, a decrease of $1.5 million in prepaid expenses and other assets, non-current and an increase of $1.0 million in severance liability, partially offset by an increase of $11.3 million in prepaid expenses and other current assets and a decrease of $0.2 million in operating lease liability. The increase in accrued research and development expenses and accounts payable were primarily due to costs associated with the development of izokibep, SLRN-517 and lonigutamab. The increase in severance liability related to our obligation to make severance payments to certain former ValenzaBio employees in connection with the Acquisition and severance obligation to the former CFO.

Cash used in operating activities in the year ended December 31, 2022 was primarily due to our net loss for the period of $64.8 million, adjusted by non-cash items of $3.3 million. Non-cash items include $4.1 million related to stock-based compensation expense, $0.2 million gain related to an amortization of premiums and discounts on short-term marketable securities and $0.5 million gain related to the change in fair value of the derivative tranche liability. The changes in operating assets and liabilities include a decrease of $4.0 million in accrued research and development expenses, an increase of $2.0 million in other non-current assets and an increase of $0.9 million in prepaid expense and other current assets, partially offset by an increase of $3.8 million in accounts payable and an increase of $3.0 million in accrued compensation and other current liabilities.

Investing Activities

Cash used in investing activities for the year ended December 31, 2023 of $447.7 million related to $956.5 million purchase of marketable securities and accrued interest, $10.0 million paid to Pierre Fabre for the amended license and commercialization agreement in connection with the Acquisition and $2.3 million purchases of fixed assets, partially offset by $373.4 million maturities of short-term marketable securities, $137.7 million in sales of marketable securities, and $10.0 million of cash acquired, net of acquisition costs, related to the Acquisition.

Cash used in investing activities for the year ended December 31, 2022 of $47.9 million related to purchases and maturities of short-term marketable securities of $176.0 million and $128.2 million, respectively, and a payment of $0.1 million in ValenzaBio acquisition costs.

Financing Activities

Cash provided by financing activities for the year ended December 31, 2023 was $568.4 million, which consisted of $574.1 million net proceeds received from issuance of common stock upon the initial public offering and $2.6 million proceeds from exercise of common stock options offset by $8.3 million taxes paid related to net share settlement of restricted stock units.

Cash provided by financing activities for the year ended December 31, 2022 of $274.3 million related to net proceeds received from the issuance of the second tranche of Series B and the first tranche of Series C redeemable convertible preferred stock shares in February and in September 2022 of $274.8 million, partially offset by a payment of $0.5 million in costs related to the initial public offering of our common stock.

Contractual Obligations and Commitments

At December 31, 2023, our material cash requirements from known contractual and other obligations primarily relate to our lease liabilities and non-cancelable purchase obligations. This presentation of non-cancellable purchase obligations does not include any estimates of potential reduction of such liabilities related to mitigation obligations of the counter-parties in the event of cancellation under the terms of our agreements. Expected timing of those payments are as follows (in thousands):

		Payments due in	
	Total	Next 12 Months	Beyond 12 Months
Lease liabilities	$ 1,848	$ 375	$ 1,473
Purchase obligation	142,344	67,567	74,777
Total payments	$ 144,192	$ 67,942	$ 76,250

Our lease liabilities are primarily related to our real estate leases for office spaces. Our outstanding non-cancelable purchase obligations primarily related to contractual commitments towards contract manufacturing organizations. Refer to Note 8 in our consolidated financial statements included in Part II Item 8 of this Annual Report on Form 10-K.

We have milestones, royalties, and/or other payments due to third parties under our existing license and collaboration agreements. See Note 7 to our audited consolidated financial statements included in Part II, Item 8 of the Annual Report on Form 10-K. During the year ended December 31, 2023, we have paid Affibody $15.0 million upon achievement of the first development milestone for izokibep under the Affibody Agreement. We could not estimate when other such payments will be due and no other such events were probable to occur as of December 31, 2023 and December 31, 2022.

Recently Issued Accounting Pronouncements

See Note 2 to our consolidated financial statements included in Part II, Item 8 of this Annual Report on Form 10-K for more information regarding recently issued accounting pronouncements.

Critical Accounting Policies and Significant Judgments and Estimates

A summary of critical accounting policies, significant judgements and estimates are disclosed in Note 2 to our consolidated financial statements for the year ended December 31, 2023 included in Part II, Item 8 of this Annual Report on Form 10-K.

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 consolidated 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 consolidated 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 fair value of derivative tranche liability, 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 consolidated financial statements, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our consolidated 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.

Valuation of Derivative Tranche Liability

In connection with the initial closing of the Series C preferred stock financing in September 2022, we had a commitment and Series C investors had an obligation to purchase the Series C Second Tranche at a fixed price, if specified conditions are met. The obligation to issue additional shares of Series C redeemable convertible preferred stock at a future date was determined to be a freestanding derivative instrument and is accounted for as a liability. The derivative tranche liability was accounted for at fair value at the issuance date and remeasured at the end of each reporting period until the shares are issued or the obligation expires. Changes in the fair value of the derivative tranche liability are recognized in the consolidated statement of operations and comprehensive loss.

The fair value of the derivative tranche liability was determined using a probability weighted model, which considered as inputs the probability of achieving tranche closing conditions, the estimated fair value of our Series C

redeemable convertible preferred stock and a discount rate. The tranche liability was to expire on June 30, 2023, if specified conditions were not met. We recognized $0.5 million for the year ended December 31, 2022, related to the change in fair value of the derivative tranche liability in our consolidated statement of operations and comprehensive loss.

The Series C Second Tranche Closing was terminated at the IPO closing, on May 9, 2023. Following the termination of the Series C Second Tranche Closing at the closing of the IPO we recognized a gain on change in fair value of the derivative tranche liability in the amount of $10.3 million in the consolidated statements of operations and comprehensive loss for the year ended December 31, 2023.

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. As of December 31, 2022, we capitalized $1.1 million of transaction costs as prepaid expenses and other non-current assets, related to the ValenzaBio Acquisition, which was accounted for as an asset acquisition. We determined that the Acquisition should be accounted for as an asset acquisition after considering whether substantially all of the fair value of the gross assets acquired was concentrated in a single asset or group of assets and whether we acquired a substantive process capable of significantly contributing to our ability to create outputs. The $1.1 million of capitalized transaction costs were recognized as research and development expense in the consolidated statements of operations and comprehensive loss for the year ended December 31, 2023.

Performance-Based Restricted Stock Unit Awards

Performance-based restricted stock units (“PSUs”), awarded to employees vest upon the achievement of certain performance milestones and market conditions (i.e., specified average stock price hurdle) at the end of specified performance periods, subject to continuous service through each respective vest date. The amount of expense recognized is based on the grant date fair value of the PSU tranche corresponding to the performance condition of the tranche which is considered probable. We estimate grant date fair value of the market portion of the PSUs based on a Monte Carlo simulation under each performance condition outcome. The Monte Carlo valuation model simulates the probabilities of stock price achievement, which requires management to make a number of assumptions including a 20-trading day volume-weighted average stock price, volatility of our peers, and the risk-free interest rate. We recognize compensation expense for each tranche of a PSU award straight-line over the period commencing on the grant date of the award and ending on the vesting date of the tranche under the PSU award. We record cumulative adjustments at each reporting date to reflect subsequent changes to the estimated outcome of the performance condition until the end of the respective performance period.

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 recognize share-based compensation expense for awards with performance conditions when it is probable that the condition will be met, and the award will vest.

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*. Prior to our IPO, the estimated fair value of the common stock underlying our stock options and stock awards was determined at each grant date by our board of directors, with assistance from management and external appraisers. All options to purchase shares of our common stock were intended to be exercisable at a price per share not less than the per-share fair value of our common stock underlying those options on the date of grant. The approach to estimate the fair value of the Company's common stock was consistent with the methods outlined in the American Institute of Certified Public Accountants' Practice Aid, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*, or Practice Aid. Subsequent to the Company's IPO, the fair value of the Company's common stock is determined based on its closing market price as reported on the Nasdaq Global Select Market.
- *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*. The expected volatility is 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 as we do not have sufficient trading history for our publicly traded common stock. 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 common stock and have no plans to pay dividends on our common stock. Therefore, we used an expected dividend yield of zero.

See Note 12 to our consolidated financial statements included in this Annual Report on 10-K 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.

We recorded stock-based compensation expense of $47.3 million, $4.1 million, and $0.2 million for the years ended December 31, 2023, 2022, and 2021, respectively. As of December 31, 2023, there was $65.5 million of total unrecognized stock-based compensation expense related to our granted options, which we expect to recognize over a remaining weighted-average period of 3.2 years. As of December 31, 2023, there was $41.7 million of total unrecognized stock-based compensation expense related to our granted restricted stock units (RSUs), which we expect to recognize over a remaining vesting term through May 2027. As of December 31, 2023, total compensation cost not yet recognized related to unvested PSUs was $65.4 million, which is expected to be recognized over a weighted-average period of 2.3 years. Total compensation cost not recognized related to unvested PSUs can increase up to $86.6 million depending on the future achievement of PSUs performance conditions.

The intrinsic value of all outstanding stock options, RSUs and PSUs as of December 31, 2023 was approximately $53.5 million, of which approximately $8.4 million related to vested stock options, RSUs and PSUs, and approximately $45.1 million related to unvested stock options, RSUs and PSUs.

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.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

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 consolidated financial statements included in this Annual Report on 10-K.

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 research and development services 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 consolidated 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 consolidated financial statements included in this Annual Report on 10-K

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 consolidated financial statements included in this Annual Report on 10-K.

Item 8. Financial Statements and Supplementary Data

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 sheets of ACELYRIN, INC. and its subsidiary (the "Company") as of December 31, 2023 and 2022, and the related statements of operations and comprehensive loss, of redeemable convertible preferred stock and stockholders' equity (deficit) and of cash flows for each of the three years in the period ended December 31, 2023, 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, 2023 and 2022, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2023 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 audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits of these financial statements in accordance with the standards of the PCAOB. 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 audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP

San Diego, California
March 28, 2024

We have served as the Company's auditor since 2022.

Consolidated Balance Sheets
(in thousands, except share and per share data)

	December 31, 2023	December 31, 2022
Assets		
Current assets		
Cash and cash equivalents	$ 218,097	$ 267,110
Short-term marketable securities	503,229	47,510
Prepaid expenses and other current assets	15,312	1,444
Total current assets	736,638	316,064
Prepaid expenses and other assets, non-current	2,678	3,859
Operating lease right-of-use asset	1,195	—
Property, plant and equipment, net	2,179	—
Total assets	$ 742,690	$ 319,923
Liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)		
Current liabilities		
Accounts payable	$ 41,920	$ 5,947
Accrued research and development expenses	35,436	5,717
Accrued compensation and other current liabilities	6,833	4,237
Severance liability	970	—
Total current liabilities	85,159	15,901
Derivative tranche liability	—	10,291
Operating lease liability, non-current	1,194	—
Total liabilities	86,353	26,192
Commitments and contingencies (Note 8)		
Redeemable convertible preferred shares, no par value; no shares authorized, issued and outstanding as of December 31, 2023; 104,461,636 shares authorized as of December 31, 2022, par value of $ 0.00001 per share; 40,743,522 shares issued and outstanding as of December 31, 2022; aggregate liquidation preference $408,000 as of December 31, 2022	—	396,593
Stockholders' equity (deficit)		
Preferred stock, 10,000,000 shares authorized, $0.00001 par value, no shares issued and outstanding at December 31, 2023; no shares authorized, issued, and outstanding at December 31, 2022		
Common stock, par value of $ 0.00001 per share; 790,000,000 and 229,461,636 shares authorized as of December 31, 2023 and 2022, respectively; 97,865,890 and 2,767,359 shares issued and outstanding as of December 31, 2023 and 2022, respectively	1	—
Additional paid-in capital	1,144,893	4,302
Accumulated other comprehensive income (loss)	162	(86)
Accumulated deficit	(488,719)	(107,078)
Total stockholders' equity (deficit)	656,337	(102,862)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	$ 742,690	$ 319,923

The accompanying notes are an integral part of these consolidated financial statements.

Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share data)

	Year Ended December 31,		
	2023	2022	2021
Operating expenses:			
Research and development	$ 355,886	$ 55,632	$ 38,230
General and administrative	66,178	13,547	3,564
Total operating expenses	422,064	69,179	41,794
Loss from operations	(422,064)	(69,179)	(41,794)
Change in fair value of derivative tranche liability	10,291	487	—
Interest income	30,555	4,052	—
Other expense, net	(423)	(132)	(45)
Net loss	$ (381,641)	$ (64,772)	$ (41,839)
Other comprehensive loss			
Unrealized gain (loss) on short-term marketable securities, net	248	(86)	—
Total other comprehensive gain (loss)	248	(86)	—
Net loss and other comprehensive loss	$ (381,393)	$ (64,858)	$ (41,839)
Net loss per share attributable to common stockholders, basic and diluted	$ (5.43)	$ (41.59)	$ (60.87)
Weighted-average common shares outstanding, basic and diluted	70,249,580	1,557,534	687,398

The accompanying notes are an integral part of these consolidated financial statements.

Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)
(in thousands, except share data)

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Gain (Loss)	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
Balance at January 1, 2021	4,056,795	$ 7,916	2,839,748	$ —	$ 1	$ (467)	$ —	(466)
Issuance of Series B redeemable convertible preferred stock for cash, net of issuance costs of $296	12,228,923	124,704	—	—		—	—	—
Stock-based compensation expense	—	—	—	—	233	—	—	233
Issuance of common stock upon exercise of options	—	—	20,284		16	—	—	16
Net loss	—	—	—	—	—	(41,839)	—	(41,839)
Balance at December 31, 2021	16,285,718	$ 132,620	$2,860,032	$ —	$ 250	$ (42,306)	$ —	$ (42,056)
Issuance of Series B redeemable convertible preferred stock, net of issuance costs of $26	12,228,923	124,974	—	—	—	—	—	—
Issuance of Series C redeemable convertible preferred stock, net of derivative liability of $10,778 and issuance costs of $223	12,228,881	138,999	—	—	—	—	—	—
Issuance of restricted stock awards	—	—	498,940	—	—	—	—	—
Repurchase and retirement of unvested founders' common stock	—	—	(591,613)	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	4,052	—	—	4,052
Net loss	—	—	—	—	—	(64,772)	—	(64,772)
Unrealized loss on short-term marketable securities, net	—	—	—	—	—	—	(86)	(86)
Balance at December 31, 2022	40,743,522	$ 396,593	2,767,359	$ —	$ 4,302	$ (107,078)	$ (86)	$ (102,862)
Issuance of common stock in connection with ValenzaBio acquisition (Note 3)	—	—	18,885,731	—	128,735	—	—	128,735
Issuance of common stock upon initial public offering, net of underwriting discounts commissions and issuance costs of $47,354	—	—	34,500,000	—	573,644	—	—	573,644
Conversion of redeemable convertible preferred stock into common stock in connection with initial public offering	(40,743,522)	(396,593)	40,743,522	1	396,592	—	—	396,593
Issuance of common stock upon settlement of restricted stock units, net of shares withheld for taxes	—	—	303,237	—	(8,325)	—	—	(8,325)
Stock-based compensation expense	—	—	—	—	47,318	—	—	47,318
Issuance of common stock under the employee stock purchase plan	—	—	24,164	—	149	—	—	149
Issuance of common stock upon exercise of options	—	—	641,877	—	2,478	—	—	2,478
Net loss	—	—	—	—	—	(381,641)	—	(381,641)
Unrealized gain on short-term marketable securities, net	—	—	—	—	—	—	248	248
Balance at December 31, 2023	—	$ —	97,865,890	$ 1	$1,144,893	$ (488,719)	$ 162	$ 656,337

The accompanying notes are an integral part of these consolidated financial statements.

Consolidated Statements of Cash Flows
(in thousands)

	Year Ended December 31,		
	2023	2022	2021
Cash flows from operating activities:			
Net loss	$ (381,641)	$ (64,772)	$ (41,839)
Adjustments to reconcile net loss to net cash used in operations:			
Stock-based compensation expense	47,318	4,052	233
Expense related to acquired in-process research and development assets	133,057	—	25,000
Net amortization of premiums and accretion of discounts on short-term marketable securities	(10,495)	(246)	—
Change in fair value of derivative tranche liability	(10,291)	(487)	—
Depreciation and amortization expense	115	—	—
Non-cash lease expense	153	—	—
Changes in assets and liabilities:			
Prepaid expense and other current assets	(11,313)	(941)	(49)
Prepaid expenses and other assets, non-current	1,528	(1,964)	—
Accounts payable	34,443	3,776	1,119
Accrued research and development expenses	24,914	(3,980)	9,697
Accrued compensation and other current liabilities	1,691	3,042	860
Operating lease liability	(154)	—	—
Severance liability	970	—	—
Net cash used in operating activities	(169,705)	(61,520)	(4,979)
Cash flows from investing activities			
ValenzaBio assets acquisition cash acquired, net of acquisition costs	10,007	—	—
Cash paid to acquire in-process research and development assets	(10,000)	—	(25,000)
Purchase of marketable securities	(956,512)	(175,970)	—
Proceeds from maturities of short-term marketable securities	373,359	128,179	—
Sales of marketable securities	137,696	—	—
Purchase of property, plant and equipment	(2,294)	—	—
Payments for ValenzaBio Acquisition costs	—	(83)	—
Net cash used in investing activities	(447,744)	(47,874)	(25,000)
Cash flows from financing activities			
Issuance of common stock upon initial public offering, net of commissions and issuance costs	574,134	—	—
Proceeds from exercise of common stock options and issuance of common stock under the employee stock purchase plan	2,627	—	16
Proceeds from the issuance of redeemable convertible preferred stock, net of issuance costs	—	263,973	124,704
Proceeds allocated to the derivative tranche liability		10,778	—
Payments for deferred offering costs	—	(489)	—
Taxes paid related to net share settlement of restricted stock units	(8,325)	—	—
Net cash provided by financing activities	568,436	274,262	124,720
Net increase (decrease) in cash and cash equivalents	(49,013)	164,868	94,741
Cash and cash equivalents, at beginning of year	267,110	102,242	7,501
Cash and cash equivalents, at end of year	$ 218,097	$ 267,110	$ 102,242

Supplemental disclosure of cash flow information:			
Conversion of 40,743,522 redeemable convertible preferred stock upon the closing of initial public offering	$ 396,593	$ —	$ —
Common stock issued in connection with ValenzaBio acquisition	$ 128,735	$ —	$ —
Right-of-use assets obtained in exchange for operating lease liability	$ 1,348	$ —	$ —
Deferred offering costs included in accrued compensation and other current liabilities and accounts payable	$ —	$ 285	$ —
ValenzaBio Acquisition costs included in accounts payable	$ —	$ 1,038	$ —

The accompanying notes are an integral part of these consolidated financial statements.

Notes to the Consolidated 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 7 for further details.

On January 4, 2023, the Company closed the acquisition of ValenzaBio, Inc. ("ValenzaBio") and issued as consideration 18,885,731 shares of its Class A common stock ("Class A Common Stock"). ValenzaBio was a privately held company developing therapies for autoimmune and inflammatory diseases. The ValenzaBio acquisition added additional assets to the Company's portfolio, including lonigutamab and SLRN-517. See Note 3 for further details.

Reverse Stock Split

In April 2023, the Company effected a reverse split of shares of the Company's outstanding common stock and redeemable convertible preferred stock at a ratio 1.972-for-1 (the "Reverse Stock Split"). The number of authorized shares and par value per share were not adjusted as a result of the Reverse Stock Split. All references to shares, restricted stock units ("RSUs") and restricted stock awards ("RSAs"), options to purchase common stock, share data, per share data, and related information contained in the consolidated financial statements have been retrospectively adjusted to reflect the effect of the Reverse Stock Split for all periods presented.

Initial Public Offering

On May 4, 2023, the Company's Form S-1 Registration Statement for its initial public offering (the "IPO") was declared effective, and on May 9, 2023, the Company closed its IPO and issued 34,500,000 shares of common stock at a price to the public of $ 18.00 per share, including 4,500,000 shares issued upon the exercise of underwriters' option to purchase additional shares of common stock. The Company received gross proceeds of $621.0 million. Net proceeds were approximately $573.6 million, after deducting underwriting discounts and commissions and offering costs of $ 47.4 million. The common stock began trading on the Nasdaq Global Select Market on May 5, 2023, under the symbol "SLRN".

Immediately prior to the IPO closing, each share of the Company's redeemable convertible preferred stock then outstanding converted into an equivalent number of shares of Class A Common Stock, and thereafter each share of Class A Common Stock then issued and outstanding was reclassified and became one share of the Company's common stock.

Liquidity

The Company has incurred significant losses and negative cash flows from operations since its inception. During the years ended December 31, 2023, 2022 and 2021, the Company incurred net losses of $381.6 million, $64.8 million and $41.8 million, respectively. The net loss of $381.6 million in the year ended December 31, 2023 includes $123.1 million of expenses related to acquired in-process research and development assets without alternative future use and $10.0 million license fee payment to Pierre Fabre incurred in connection with the ValenzaBio acquisition. As of December 31, 2023, the Company had an accumulated deficit of $488.7 million. Cash used in operating activities was $169.7 million, $61.5 million and $5.0 million for the years ended December 31, 2023, 2022 and 2021, respectively.

The Company has historically financed its operations primarily through the sale of shares of its redeemable convertible preferred stock in private placements and the sale of shares of its common stock in its IPO. As of December 31, 2023, the Company had cash and cash equivalents and short-term marketable securities of $721.3 million. The Company does not have any products approved for sale and has not generated any revenue from product sales to date. 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. Management expects that its cash and cash equivalents and short-term marketable securities will be sufficient to fund its current operating plan and capital expenditure requirements for at least the next 12 months from the date of issuance of these consolidated financial statements.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") and include operations of the Company and its wholly owned subsidiary, WH 2 LLC (the legal successor of ValenzaBio). These subsidiaries were formed in contemplation of the Acquisition and did not have any operations and any balances from inception to December 31, 2023.

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 derivative tranche liability, the fair value of its common stock, stock-based compensation expense, accruals for research and development expenses, fair value of in-process research and development assets acquired, 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 or assumptions.

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 and Cash Equivalents

The Company considers all highly liquid investments with original maturities of three months or less from the date of purchase to be cash equivalents. As of December 31, 2023 and 2022, the Company's cash was deposited in a checking and money market account.

Short-Term Marketable Securities

Investments with original maturities of greater than 90 days are classified as available-for-sale marketable securities and consist primarily of U.S. Treasury obligations, corporate debt obligations and federal agency obligations. As the Company's entire investment portfolio is considered available for use in current operations, the Company classifies all investments as available-for-sale and as current assets, even though the stated maturity may be more than one year from the current balance sheet date. Available-for-sale securities are carried at fair value, with unrealized gains and losses reported

in accumulated other comprehensive loss, which is a separate component of stockholders' equity (deficit) in the consolidated balance sheet.

Interest income includes interest, amortization of purchase premiums and discounts, realized gains and losses on sales of securities and other-than-temporary declines in the fair value of investments, if any.

The amortized cost of securities is adjusted for amortization of premiums and accretion of discounts to maturity, which are both recorded to interest income in the Company's consolidated statement of operations and comprehensive loss.

Changes in the fair value of available-for-sale securities impact the consolidated statement of operations and comprehensive loss only when such securities are sold if an allowance for credit losses is recognized or if an impairment is recognized. Realized gains and losses on the sale of securities are determined by specific identification of each security's cost basis. The Company regularly reviews its investment portfolio to determine if any security is impaired, which would require the Company to record an allowance for credit losses or impairment charge in the period any such determination is made. In making this judgment, the Company evaluates, among other things, the duration and extent to which the fair value of a security is less than its cost, its intent to sell or whether it is more likely than not that the Company will be required to sell the security before recovery of its amortized cost basis, the financial condition of the issuer and any changes thereto, and, as necessary, the portion of a decline in fair value that is credit-related. This assessment could change in the future due to new developments or changes in assumptions related to any particular security. Realized gains and losses, allowances for credit losses and impairments on available-for-sale securities, if any, are recorded to interest expense, net in the consolidated statement of operations and comprehensive loss.

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 cash equivalents, prepaid expenses and other current assets, accounts payable, accrued expenses and other liabilities, approximate fair value due to their short-term maturities. Financial instruments, such as money market funds, short-term marketable securities and derivative tranche liability are measured at fair value at each reporting date (see Note 4).

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. The Company recognizes transfers into and out of levels within the fair value hierarchy in the period in which the actual event or change in circumstances that caused the transfer occurs.

Concentration of Credit Risk

Cash and cash equivalents, and short-term marketable securities are financial instruments that potentially subject the Company to concentrations of credit risk. As of December 31, 2023 and 2022, cash consists of cash deposited with one

financial institution and account balances exceed federally insured limits. Management believes that the Company is not exposed to significant credit risk due to the financial strength of this institution.

The Company also has investments in money market funds, U.S. Treasury obligations, corporate debt obligations, and federal agency obligations, which can be subject to certain credit risks. The Company mitigates the risks by investing in high-grade instruments, limiting its exposure to any one issuer and monitoring the ongoing creditworthiness of the financial institutions and issuers. The Company has not experienced any losses on its financial instruments.

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 manufacturing of clinical supplies for 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 made by or 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 consolidated 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. The Company determined that ValenzaBio acquisition should be accounted for as an asset acquisition after considering whether substantially all of the fair value of the gross assets acquired was concentrated in a single asset or group of assets and whether the Company acquired a substantive process capable of significantly contributing to the Company's ability to create outputs.

The fair value of in-process research and development assets is determined based on the present value of future discounted cash flows.

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.

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. Following the Company's IPO that was closed on May 9, 2023, all redeemable convertible preferred stock shares were converted to the Company's common stock shares.

Derivative Tranche Liability

In connection with the initial closing of the Series C preferred stock financing in September 2022, the Company had a commitment and Series C investors had an obligation to purchase the Series C Second Tranche at a fixed price, if specified conditions were met on June 30, 2023. The obligation to issue additional shares of Series C redeemable convertible preferred stock at a future date was determined to be a freestanding derivative instrument and was accounted for as a liability. The derivative tranche liability was accounted for at fair value at the issuance date and remeasured at the end of each reporting period until the shares are issued or the obligation expires. Changes in the fair value of the derivative tranche liability are recognized in the consolidated statement of operations and comprehensive loss.

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 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 have begun to be incurred or if the Company underestimates or overestimates 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-based equity awards including restricted stock awards, restricted stock units, performance-based restricted stock units, and stock options to employees 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.

Performance-based restricted stock units (“PSUs”), awarded to employees vest upon the achievement of certain performance milestones and market conditions (i.e., specified average stock price hurdle) at the end of specified

performance periods, subject to continuous service through each respective vest date. The amount of expense recognized is based on the grant date fair value of the PSU tranche corresponding to the performance condition of the tranche which is considered probable. The estimated grant date fair value of the market portion of the PSUs is based on a Monte Carlo simulation under each performance condition outcome. The Monte Carlo valuation model simulates the probabilities of stock price achievement, which requires management to make a number of assumptions including a 20-trading day volume-weighted average stock price, volatility of our peers, and the risk-free interest rate. Compensation expense for each tranche of a PSU award is recognized straight-line over the period commencing on the grant date of the award and ending on the vesting date of the tranche under the PSU award. Cumulative adjustments are recorded at each reporting date to reflect subsequent changes to the estimated outcome of the performance condition until the end of the respective performance period.

The Company uses the Black-Scholes option pricing model to determine the fair value of stock options and restricted stock awards if these are similar to early exercised 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. The Company estimates the fair value of restricted stock units based on the fair value of the Company's common stock at a grant date.

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 consolidated financial statements or tax returns. Deferred tax assets and liabilities are determined based on the difference between the consolidated 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, 2023 and 2022, 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.

Comprehensive Loss

Comprehensive loss includes net loss as well as other changes in stockholders' equity (deficit) that result from transactions and economic events other than those with stockholders. The Company's other comprehensive income (loss) is comprised solely of unrealized gains (losses) on available-for-sale marketable securities. The Company has not recorded any reclassifications from other comprehensive income (loss) to net loss during the period presented.

Leases

The Company adopted ASU 2016-02, "Leases (Topic 842)" accounting standard as of January 1, 2022. The contractual arrangements that meet the definition of a lease are classified as operating or finance leases and are recorded on the balance sheets as both a right-of-use asset ("ROU asset") and lease liability, calculated by discounting fixed lease payments over the lease term at the rate implicit in the lease or the Company's incremental borrowing rate ("IBR"). Lease ROU assets and lease obligations are recognized based on the present value of the future minimum lease payments over the lease term at the lease commencement date. The Company currently does not have any finance leases.

Operating lease ROU assets are adjusted for (i) payments made at or before the commencement date, (ii) initial direct costs incurred, and (iii) tenant incentives under the lease. As the implicit rate for the operating leases are not determinable, the Company determines its IBR based on the information available at the applicable lease commencement date. The IBR is determined by using the rate of interest that the Company would pay to borrow on a collateralized basis an amount equal to the lease payments for a similar term and in a similar economic environment where the asset is located. The Company considers a lease term to be the noncancelable period that it has the right to use the underlying asset, including any periods where it is reasonably certain the Company will exercise any option to extend the contract.

Lease costs for minimum lease payments for operating leases are recognized on a straight-line basis over the lease term. Lease liabilities are increased by interest and reduced by payments each period, and the ROU asset is amortized over the lease term. Variable lease costs are recorded when incurred. In measuring the ROU assets and lease liabilities, the Company has elected to combine lease and non-lease components. The Company excludes short-term leases, if any, having initial terms of 12 months or less at lease commencement as an accounting policy election, and recognizes rent expense on a straight-line basis over the lease term for these types of leases.

The Company did not have any leases as of and prior to January 1, 2023.

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.

In November 2023, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures, which requires all public entities, including public entities with a single reportable segment, to provide in interim and annual periods one or more measures of segment profit or loss used by the chief operating decision maker to allocate resources and assess performance. In addition, this guidance requires disclosures of significant segment expenses and other segment items as

well as incremental qualitative disclosures. This guidance is effective for fiscal years beginning after December 15, 2023, and interim periods after December 15, 2024, with retrospective application required, and early adoption permitted. The Company is currently in the process of evaluating the effects of this guidance on its related disclosures.

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures, which requires enhanced income tax disclosures, including specific categories and disaggregation of information in the effective tax rate reconciliation, disaggregated information related to income taxes paid, income or loss from continuing operations before income tax expense or benefit, and income tax expense or benefit from continuing operations. This guidance is effective for annual periods beginning after December 15, 2024, with early adoption permitted. The Company is currently in the process of evaluating the impact of this pronouncement on its related disclosures.

3. ValenzaBio Acquisition

On December 20, 2022, the Company entered into the Agreement and the Plan of Merger and Reorganization (the “Merger Agreement”) to acquire ValenzaBio. In connection with the planned ValenzaBio acquisition, the Company formed two wholly owned subsidiaries, WH1, Inc. and WH2 LLC in November 2022. Through the two-step merger and restructuring, WH1 Inc. was merged with and into ValenzaBio with WH1 Inc. ceasing to exist, and ValenzaBio was then merged with and into WH2 LLC, with WH2 LLC continuing as the legal successor to ValenzaBio. (the “Acquisition”). The Acquisition closed on January 4, 2023 (the “Closing Date”).

The Company concluded that the Acquisition is an asset acquisition as substantially all of the fair value of the gross assets acquired, excluding cash, was concentrated in a single asset, lonigutamab, and the Company did not acquire a workforce or any substantive process capable of significantly contributing to the ability to create outputs.

As consideration, the Company issued 18,885,731 shares of its Class A Common Stock to ValenzaBio stockholders, of which 2,013,673 were being held by Seller LLC for any post-acquisition costs and general indemnities for 12 months from the Closing Date ("Holdback Release Date"), and paid $7,663 in cash to one non-accredited investor. Additionally, $ 0.1 million is payable in cash to Seller LLC to cover Seller LLC’s fees and expenses related to the Acquisition, with any unused amount to be released to ValenzaBio stockholders as soon as practicable following the completion of Seller LLC’s responsibilities. The Company also incurred $1.2 million of acquisition-related costs that were included in the total consideration and capitalized to assets acquired.

The Company assumed options of certain ValenzaBio option holders who entered into consulting agreements with the Company, which became options for the purchase of an aggregate of 1,249,811 shares of the Company’s Class A Common Stock upon the closing of the Acquisition on January 4, 2023. The assumed options vested in full on March 31, 2023. Each assumed option is exercisable until the earlier of (i) 12 months following the termination of the option holder’s continuous service with the Company, or (ii) the original expiration date of such assumed option.

Outstanding ValenzaBio shares were exchanged into shares of the Company's Class A Common Stock and the options described above assumed at an exchange ratio of 0.8027010-for-one.

The following table represents the total purchase consideration (in thousands):

Issued Class A Common Stock (1)	$	128,735
Transaction costs (2)		1,271
Cash (3)		8
Total	$	130,014

(1) Shares were issued for consideration at $ 6.86 per share, including 2,013,673 shares that were being held by Seller LLC until the Holdback Release Date. The Company used a third party valuation specialist to assist management in determining the fair value of the shares of Class A Common Stock at the Closing Date.

(2) Legal and advisory transaction costs of $ 1.3 million incurred by the Company in connection with the Acquisition, including $ 0.1 million payable in cash to Seller LLC for the expense fund.

(3) Cash payment of $7,663 to one non-accredited investor for settlement of vested ValenzaBio options.

The following is the allocation of the purchase consideration to the acquired assets and liabilities (in thousands):

Cash	$	11,369
Prepaid expenses and other current assets		2,074
In-process research and development assets		123,057
Accounts payable		(1,628)
Accrued research and development expenses		(4,805)
Accrued compensation and other current liabilities		(53)
Total net asset acquired	$	130,014

In-process research and development ("IPR&D) assets were related to acquired product candidates: lonigutamab in clinical trials and SLRN-517 in preclinical development. The fair value of in-process research and development assets was based on the present value of future discounted cash flows, which was based on significant estimates. These estimates included the number of potential patients and market prices of future product candidates, costs required to conduct clinical trials, future milestones and royalties payable under acquired license agreements, costs to receive regulatory approval and potentially commercialize product candidates, as well as estimates for probability of success and the discount rate. The estimated fair values of lonigutamab and SLRN-517 assets were $114.8 million and $8.2 million, respectively. The Company concluded that acquired assets do not have an alternative future use and recognized the full amount of $123.1 million as research and development expenses in the consolidated statement of operations and comprehensive loss in January 2023.

There are a number of additional obligations under the Merger Agreement that are separate from the assets and liabilities acquired, including the following:

Assumed options. The assumed options, discussed above, did not have substantive service requirement, and were accounted as a separate transaction from the Acquisition. The fair values of assumed options of $3.1 million and $1.8 million was expensed as research and development and general and administrative expenses, respectively, in the consolidated statement of operations and comprehensive loss for the year ended December 31, 2023.

Settled equity awards. In accordance with the severance obligations of ValenzaBio and per the terms of the Merger Agreement, certain unvested options and restricted stock awards of former ValenzaBio employees, who did not enter into consulting agreements with the Company, were accelerated and net exercised upon the closing of the Acquisition and termination of employment of such ValenzaBio employees. The fair value of unvested equity awards of $0.9 million was expensed as general and administrative expense in the consolidated statement of operations and comprehensive loss for the year ended December 31, 2023. Payments in cash to one non-accredited investor for settlement of unvested ValenzaBio options and one former ValenzaBio employee to whom options were promised but not granted at the Closing Date of $8,387 and $30,000, respectively, were expensed as general and administrative expenses in the consolidated statement of operations and comprehensive loss for the year ended December 31, 2023.

Severance payment obligation. In accordance with the severance plan of ValenzaBio, the Company is obligated to make severance payments to certain former ValenzaBio employees of approximately $5.1 million, including estimated taxes, for a period of three to 18 months from the Closing Date, depending on the position and tenure of such employees with ValenzaBio. The Company recognized the estimated fair value of severance payments obligations of $2.5 million and $2.4 million at the Closing Date as research and development and general and administrative expenses, respectively, in the consolidated statement of operations and comprehensive loss for the year ended December 31, 2023. The fair value of severance payments obligations was estimated based on future expected cash flows discounted to the Closing Date and a discount rate of 8%. The Company will accrete the fair value of severance payments obligations to the amounts payable over the obligation period as either research and development or general and administrative expenses based on the former employees' functional department.

As of December 31, 2023, severance payments obligations to ValenzaBio employees in the amount of $ 0.3 million were included in the consolidated balance sheet. The accretion of severance payments obligations of $0.1 million were

included in each of research and development and general and administrative expenses, respectively, in the consolidated statement of operations and comprehensive loss for the year ended December 31, 2023.

Amendment to Pierre Fabre Agreement. The Company, ValenzaBio and Pierre Fabre Medicament SAS ("Pierre Fabre") entered into an amendment to the license and commercialization agreement, which became effective on the Closing Date. The Company paid a $10.0 million non-refundable license fee to Pierre Fabre. See Note 7 for additional details.

4. Fair Value Measurements

The Company's financial instruments measured at fair value on a recurring basis consist of Level 1, Level 2, and Level 3 financial instruments. Usually, short-term marketable securities are considered Level 2 when their fair values are determined using inputs that are observable in the market or can be derived principally from or corroborated by observable market data such as pricing for similar securities, recently executed transactions, cash flow models with yield curves, and benchmark securities. In addition, Level 2 financial instruments are valued using comparisons to like-kind financial instruments and models that use readily observable market data as their basis. Corporate debt obligations, commercial paper, government agency obligations and asset-backed securities are valued primarily using market prices of comparable securities, bid/ask quotes, interest rate yields and prepayment spreads and are included in Level 2.

Financial assets and liabilities are considered Level 3 when their fair values are determined using pricing models, discounted cash flow methodologies, or similar techniques, and at least one significant model assumption or input is unobservable.

The following table sets forth the Company's financial instruments that were measured at fair value on a recurring basis by level within the fair value hierarchy (in thousands):

	Fair Value Measurements as of December 31, 2023			
	Total	Level 1	Level 2	Level 3
Assets:				
Money market funds (included in cash and cash equivalents)	$ 23,205	$ 23,205	$ —	$ —
U.S. Treasury obligations ($146,497 included in cash and cash equivalents)	525,353	—	525,353	—
Corporate debt obligations ($23,313 included in cash and cash equivalents)	135,284	—	135,284	—
Federal agency obligations ($15,344 included in cash and cash equivalents)	27,746	—	27,746	—
Total fair value of assets	$ 711,588	$ 23,205	$ 688,383	$ —

	Fair Value Measurements as of December 31, 2022			
	Total	Level 1	Level 2	Level 3
Assets:				
Money market funds (included in cash and cash equivalents)	$ 238,223	$ 238,223	$ —	$ —
U.S. Government bonds	25,459	—	25,459	—
U.S. Treasury bills	11,404	11,404	—	—
Corporate debt obligations	2,141	—	2,141	—
Federal agency obligations	8,506	—	8,506	—
Total fair value of assets	$ 285,733	$ 249,627	$ 36,106	$ —
Liabilities:				
Derivative tranche liability	$ 10,291	$ —	$ —	$ 10,291
Total fair value of liabilities	$ 10,291	$ —	$ —	$ 10,291

Classified as:	December 31, 2023	December 31, 2022
Cash and cash equivalents	$ 208,359	$ 238,223
Short-term marketable securities	503,229	47,510
Total cash equivalents and marketable securities	$ 711,588	$ 285,733

The following table sets forth the changes in the fair value of Level 3 liabilities (in thousands):

Derivative Tranche Liability	2023	2022
Balance as of January 1st	$ 10,291	$ —
Fair value of derivative tranche liability upon issuance	—	10,778
Change in fair value	(10,291)	(487)
Balance as of December 31st	$ —	$ 10,291

The derivative tranche liability was issued on September 9, 2022 with a fair value of $ 10.8 million. The fair value of the derivative tranche liability has been estimated using a probability weighted model. Upon the closing of the IPO, on May 9, 2023, the derivative tranche liability was remeasured at fair value based on its intrinsic value and it was terminated. Intrinsic value was calculated as a difference between the IPO price of $18.00 per share and $12.2661, the Series C second tranche closing per share purchase price. The fair value of the derivative tranche liability upon the closing of the IPO was determined to be zero and the Series C Second Tranche Closing was terminated.

The following significant assumptions were used to estimate fair value of the derivative tranche liability as of December 31, 2022:

Probability of achieving specified conditions	80 %
Fair value of Series C preferred stock share	$ 12.2661
Discount rate	25 %

5. Available-For-Sale Marketable Securities

The following tables summarize the estimated fair value of the Company's available-for-sale marketable securities as of December 31, 2023 and 2022 (in thousands):

As of December 31, 2023	Total Amortized Cost	Total Unrealized Gain	Total Unrealized Loss	Total Estimated Fair Value
Money market funds (included in cash and cash equivalents)	$ 23,205	$ —	$ —	$ 23,205
U.S. Treasury obligations ($146,497 included in cash and cash equivalents)	525,198	156	(1)	525,353
Corporate debt obligations ($23,313 included in cash and cash equivalents)	135,288	36	(40)	135,284
Federal agency obligations ($15,344 included in cash and cash equivalents)	27,735	12	(1)	27,746
Total available for sale marketable securities	$ 711,426	$ 204	$ (42)	$ 711,588

As of December 31, 2022	Total Amortized Cost	Total Unrealized Loss[1]	Total Estimated Fair Value
Money market funds (included in cash and cash equivalents)	$ 238,223	$ —	$ 238,223
U.S. Government bonds	25,506	(47)	25,459
U.S. Treasury obligations	11,430	(26)	11,404
Corporate debt obligations	2,145	(4)	2,141
Federal agency obligations	8,515	(9)	8,506
Total available for sale marketable securities	$ 285,819	$ (86)	$ 285,733

(1) The Company did not have any gross unrealized gains as of December 31, 2022.

As of December 31, 2023 and 2022, no significant facts or circumstances were present to indicate a deterioration in the creditworthiness of the issuers of the marketable securities, and the Company has no requirement or intention to sell these securities before maturity or recovery of their amortized cost basis. The Company considered the current and expected future economic and market conditions and determined that its investments were not significantly impacted. For all securities with a fair value less than its amortized cost basis, the Company determined the decline in fair value below amortized cost basis to be immaterial and non-credit related, and therefore no allowance for losses has been recorded. During the years ended December 31, 2023, 2022, and 2021, the Company did not recognize any impairment losses on its investments.

The Company presents accrued interest receivable related to the available-for-sale marketable securities in prepaid expenses and other current assets, separate from short-term investments in the consolidated balance sheet. As of December 31, 2023 and 2022, accrued interest receivable was $0.8 million and $0.1 million, respectively. The Company's accounting policy is to not measure an allowance for credit losses for accrued interest receivables and to write-off any uncollectible accrued interest receivable as a reversal of interest income in a timely manner, which it considers to be in the period in which the Company determines the accrued interest will not be collected. The Company has not written off any accrued interest receivables for the years ended December 31, 2023, 2022, and 2021.

As of December 31, 2023, all available-for-sale marketable securities mature within one year.

6. Consolidated Balance Sheet Components

Prepaid expenses and other current assets

Prepaid expenses and other current assets consist of the following (in thousands):

	As of December 31,	
	2023	2022
Prepaid research and development expenses	$ 8,184	$ 682
Value-Added Tax (VAT) receivable	3,985	—
Prepaid insurance and other current assets	1,712	86
Interest receivable	764	138
Prepaid other services	667	288
Research and development credit receivable	—	250
	$ 15,312	$ 1,444

Prepaid expenses and other assets, non-current

Other non-current assets consist of the following (in thousands):

	As of December 31,	
	2023	2022
Prepaid research and development expenses, non-current	$ 2,644	$ 1,964
Security deposits	34	—
Acquisition transaction costs	—	1,121
Deferred IPO offering costs	—	774
	$ 2,678	$ 3,859

Property, plant and equipment, net

Property, plant and equipment consisted of the following as of December 31, 2023 (in thousands)：

	December 31, 2023
Construction in progress	$ 1,460
Computer and other equipment	407
Furniture and fixtures	306
Leasehold improvements	121
Total property, plant and equipment, gross	2,294
Less: accumulated depreciation and amortization	(115)
Property, plant and equipment, net	$ 2,179

There was no property, plant and equipment balance as of December 31, 2022.

Accrued research and development expenses

Accrued research and development expenses are comprised of the following (in thousands):

	As of December 31,	
	2023	2022
Accrued clinical manufacturing expenses	$ 22,232	$ 1,292
Accrued clinical expenses	13,204	4,425
	$ 35,436	$ 5,717

Accrued compensation and other current liabilities

Accrued compensation and other current liabilities are comprised of the following (in thousands):

	As of December 31,	
	2023	2022
Accrued compensation	$ 5,417	$ 3,068
Accrued professional services fees (1)	1,099	808
Other accrued expenses and current liabilities	317	361
	$ 6,833	$ 4,237

(1) IPO offering costs included in accrued liabilities were zero and $0.2 million as of December 31, 2023 and December 31, 2022, respectively.

7. 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 consolidated statements 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. In November 2023, the Company paid a total amount of $15.0 million in relation with attaining one of the development milestones described above and recorded the payment within research and development expenses in the consolidated statement of operations and comprehensive loss for the year ended December 31, 2023. Royalties will be recognized as cost of sales when products are sold and royalties are payable. No other milestone or royalties were probable and estimable as of December 31, 2023 and 2022.

Pierre Fabre License and Commercialization Agreement

Upon the closing of the Acquisition, the Company became the successor to ValenzaBio's rights under the March 25, 2021 license and commercialization agreement between ValenzaBio and Pierre Fabre, as amended (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. The 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 the Company from using the licensed intellectual property in any antibody drug conjugate, multi-specific antibodies or any other derivatives of lonigutamab.

In the event the Company decides 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 the Company has the right of first negotiation to acquire such development and commercialization rights as to that territory, or Pierre Fabre has the right to require the Company to buy out its right to the option for a one-time payment of $31.0 million or the Company has 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 the Company buys out Pierre Fabre's right to the option, the option will expire or terminate, respectively. The Company is 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 consideration for the amendment to the Pierre Fabre Agreement, which became effective upon the closing of the Acquisition (see Note 3), the Company paid Pierre Fabre an aggregate license payment of $10.0 million. The Company is 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 the Company enters into a sublicense with a third party, the Company 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 relates to.

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 the Company or any of its affiliates institutes a patent challenge against the licensed patents from Pierre Fabre. The Company 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.

As of December 31, 2023, no milestones were probable and accrued in the consolidated balance sheet. The payment of $ 10.0 million for additional license fees was recorded as research and development expenses in the consolidated statement of operations and comprehensive loss for the year ended December 31, 2023.

Novelty Nobility License and Commercialization Agreement

Upon the closing of the Acquisition, 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 SLRN-517, an unmodified IgG1 monoclonal antibody, as a therapeutic treatment.

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.

The Novelty License Agreement is effective on a licensed product-by-licensed product and country-by-country basis until the expiration of the latest to expire royalty term, unless early terminated. The royalty term, with respect to a licensed product and a country is the period commencing on the first commercial sale of such product in such country, and ending upon the latest to occur of: a) there being no patent right in such country that had at least one valid claim covering the licensed product in whole or in part, or the manufacture or use thereof; b) 10 years from the first commercial sale of such product worldwide; or c) expiration of regulatory exclusivity for such product in such country. The agreement can be early terminated upon (i) a material breach, (ii) abandonment of development by the Company, in which the Company ceases all development activities for the licensed product, (iii) termination by patent challenge, and (iv) insolvency. The Company may terminate the contract at any point, upon 30 days prior written notice to Novelty Nobility, Inc.

As of December 31, 2023, no milestones were probable and accrued in the consolidated balance sheet.

8. Commitments and Contingent Liabilities

License Agreement

The Company is required to pay certain milestones upon the achievement of specific development and regulatory events, upon products' commercialization and products' royalties under its license agreements, including its agreements with Affibody, Pierre Fabre, Novelty Nobility and other non-exclusive license agreements. None of the milestones, other than the $15.0 million Afiibody milestone disclosed in Note 7, were achieved or probable, all products were in development, as such, no milestones or royalties were accrued in the condensed consolidated balance sheets as of December 31, 2023 and 2022.

Research and Development Agreements

The Company enters into various agreements in the ordinary course of business, such as those with suppliers, contract research organizations, contract manufacturing organizations, and clinical trial sites. These contracts generally provide for termination on notice or may have a potential termination fee if a purchase order is canceled within a specified time. The total value of non-cancellable obligations under contracts was $142.3 million and $0.1 million as of December 31, 2023 and 2022, respectively. This presentation of non-cancellable purchase obligations does not include any estimates of potential reduction of such liabilities related to mitigation obligations of the counter-parties in the event of cancellation under the terms of our engagements. During both fiscal years there were no amounts accrued related to termination and cancellation charges in the consolidated balance sheets, as the Company has not determined cancellation to be probable. Non-cancelable purchase obligations for services to be performed or product to be manufactured, as of December 31, 2023 amount to:

2024	67,567
2025	53,686
2026	20,985
2027 and thereafter	106
Total	$ 142,344

Lease

In January 2023, the Company entered into a lease agreement to rent approximately 10,012 square feet of office space in Agoura Hills, California. The term of the lease is 65 months with an option to extend it for an additional three years. Monthly rent payments are approximately $30,500, subject to an annual 3.0% increase and six months rental abatement during the first year. In addition to the base rent, the Company is obligated to pay variable costs related to its share of operating expenses and taxes. In connection with the lease agreement, the Company made a security deposit $34,000 that is included in prepaid expenses and other assets, non-current in the consolidated balance sheet as of December 31, 2023.

As of the lease commencement date the Company recorded $ 1.3 million as right-of-use ("ROU") asset and operating lease liability, non-current, in the consolidated balance sheet.

In July 2023, the Company entered into a lease agreement to rent approximately 22,365 square feet of office space in South San Francisco with the commencement date to be determined upon completion of work to be performed by the landlord. The term of the lease is 60 months with an option to extend it for an additional three years at then current market rates. Monthly base rent payments are approximately $150,000, subject to an annual 3.5% increase and a share of building operating expenses. The lease has not commenced as of December 31, 2023.

Operating lease costs were $0.3 million for the year ended December 31, 2023, and were recorded in general and administrative expenses and research and development expenses in the consolidated statements of operations and comprehensive loss. During the year ended December 31, 2023, the Company recognized a total of $0.1 million in expense related to short-term leases recorded as general administrative expense in the consolidated statements of operations and comprehensive loss.

The following table summarizes a maturity analysis of the Company's operating lease liabilities showing the aggregate lease payments as of December 31, 2023 (in thousands):

2024	375
2025	386
2026	398
2027	409
2028	280
Total future lease payments	1,848
Less imputed interest	(434)
Total operating lease liability balance	1,414
Less current portion of lease liability (included in accrued compensation and other current liabilities)	(220)
Operating lease liability, non-current	$ 1,194

The weighted-average remaining lease term was 56 months and the weighted-average discount rate was 12%.

Cash paid for amounts included in the measurement of lease liabilities was less than $ 0.1 million.

Legal Contingencies

On November 15, 2023, a purported federal securities class action lawsuit was commenced in the United States District Court for the Central District of California. An amended complaint was filed on March 26, 2024 (Boukadoum v. Acelyrin, Inc. et al., No. 2:23-cv-09672-FMO-MAA), naming us and current and former executive officers and directors as

defendants. The complaint alleges that the defendants violated the Exchange Act and Securities Act by misleading investors about the Phase 2b trial of izokibep in HS. The original complaint was filed following our announcement of the week 16 results from the Part B portion of such Phase 2b trial. The complaint seeks damages and an award of reasonable costs and expenses, including attorneys' fees, expert fees and other costs, as well as such other and further relief as the court may deem just and proper.

It is possible that additional suits will be filed, or allegations made by stockholders, with respect to these same or other matters and also naming the Company and/or its officers and directors as defendants. This lawsuit and any other potential lawsuits are subject to inherent uncertainties, and the actual defense and disposition costs will depend upon many unknown factors. The outcome of this lawsuit is necessarily uncertain. The Company could be forced to expend significant resources in the defense against this and any other related lawsuits and the Company may not prevail. The Company currently is not able to estimate the possible loss to the Company from this lawsuit, as this lawsuit is currently at an early stage, and such amounts could be material to the Company's financial statements even if the Company prevails in the defense against this lawsuit. The Company cannot be certain how long it may take to resolve this lawsuit or the possible amount of any damages that the Company may be required to pay. The Company does not consider any payment to be probable or reasonably estimable and has not accrued for any potential liability relating to this lawsuit.

From time to time, the Company may become involved in additional legal proceedings or be subject to claims arising in 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 is required to determine both probability and the estimated amount.

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, 2023, the Company did not have any material indemnification claims that were probable or reasonably possible and consequently has not recorded related liabilities.

9. Redeemable Convertible Preferred Stock

In October 2021, the Company entered into a Series B stock purchase agreement and issued 12,228,923 shares of its Series B redeemable convertible preferred stock (the "Series B Stock") at a price of $10.2217 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 12,228,923 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.

In February 2022, the Company closed the Series B Second Tranche financing and issued 12,228,923 shares of Series B redeemable convertible preferred stock (the "Series B Stock") at a price of $10.2217 per share for gross cash proceeds of $125.0 million and incurred less than $0.1 million issuance costs.

In September 2022, the Company entered into a Series C stock purchase agreement and issued 12,228,881 shares of Series C redeemable convertible preferred stock (the "Series C Stock") at a price of $12.2661 per share for gross cash proceeds of $150.0 million (the "Series C First Tranche Closing") and incurred issuance costs of $0.2 million.

Pursuant to the Series C preferred stock purchase agreement, the Company and investors agreed to issue and purchase an additional 12,228,881 shares of Series C Stock at the same purchase price of $12.2661 per share on June 30,

2023, subject to meeting certain conditions (the "Series C Second Tranche Closing") (see Note 10). If a Series C Stock holder did not purchase the full number of the Series C Second Tranche shares that was required to be purchased by it on the Series C Second Tranche Closing date and this holder became a defaulting purchaser, then each 10 shares of Series C Stock held by such holder would have automatically converted into one share of Class A Common Stock, as adjusted for any stock dividends, splits, recapitalizations and the like in accordance with the Company's then-current certificate of incorporation.

On May 9, 2023, the IPO closing date, each share of the Company's redeemable convertible preferred stock then issued and outstanding automatically converted into one share of the Company's Class A Common Stock, thereafter each share of Class A Common Stock then issued and outstanding was reclassified and became one share of common stock and the Series C Second Tranche Closing was terminated.

The authorized, issued, and outstanding shares of the Company's convertible preferred stock and liquidation preferences as of December 31, 2022 were as follows (in thousands, except for share amounts):

	December 31, 2022			
	Shares Authorized	Shares Issued and Outstanding	Aggregate Liquidation Preference	Net Carrying Value
Series A redeemable convertible preferred stock	8,000,000	4,056,795	$ 8,000	$ 7,916
Series B redeemable convertible preferred stock	48,230,900	24,457,846	250,000	249,678
Series C redeemable convertible preferred stock	48,230,736	12,228,881	150,000	138,999
Total redeemable convertible preferred stock	104,461,636	40,743,522	$ 408,000	$ 396,593

The significant rights, preferences and privileges of the Company's redeemable convertible preferred stock were as follows:

Dividends — The holders of Series A Stock, Series B Stock and Series C Stock were 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 years ended December 31, 2023, 2022, and 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 C Stock and Series B Stock were entitled to receive, before any payments were made to the holders of Series A Stock or common stock, an amount per share equal to the greater of: (i) Series C Stock and the Series B Stock original issuance price of $12.2661 and $10.2217, respectively, plus any dividends declared but unpaid; or (ii) such amount per share as would have been payable had all shares of Series C Stock and Series 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 C Stock and Series B Stock liquidation preference, the funds were to be distributed with equal priority and pro rata among the holders of the Series C Stock and Series B Stock in proportion to the preferential amount each holder was otherwise entitled to receive.

After full payment to holders of the Series C Stock and 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 $ 1.9720, 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 were to be distributed with equal priority and pro rata among the holders of the Series A Stock in proportion to the preferential amount each holder was otherwise entitled to receive.

After the payment to the holders of Series C Stock, Series B Stock and Series A Stock of the full preferential amounts, the entire remaining assets of the Company legally available for distribution were to be distributed with equal

priority and pro rata among the holders of common stock in proportion to the number of shares of common stock held by them.

Conversion — Each share of Series A Stock, Series B Stock and Series C Stock was 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, Series B Stock and Series C Stock original issuance price, $1.9720, $10.2217 and $12.2661, respectively, divided by the Series A Stock, Series B Stock and Series C Stock conversion price in effect at the time of conversion. If, after the issuance date of the Series A Stock, Series B Stock and Series C Stock, the Company were to issue or sell, or was 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 or Series C Stock, except for certain exceptions, the conversion price of the Series A Stock and/or the Series B Stock and Series C Stock would be adjusted. The Series A Stock, Series B Stock and Series C Stock conversion prices were initially equal to the Series A Stock, Series B Stock and Series C Stock original issue prices, and were subject to recapitalization and other adjustments, as provided in the Company's then-current certificate of incorporation. As of December 31, 2022, the conversion rates were one-for-one.

Voting Rights — The holders of redeemable convertible preferred stock and the holders of common stock were to vote together and not as separate classes. Each holder of Series A Stock, Series B Stock and Series C Stock was entitled to the number of votes equal to the number of shares of common stock into which the shares of Series A Stock, Series B Stock and Series C Stock could be converted as of the record date.

For as long shares of redeemable convertible preferred stock remained outstanding, Series A stockholders, Series B stockholders and Series C stockholders, voting as a separate class, were entitled to elect Series A, Series B and Series C members of the Board and had certain protective provisions, as defined in the then-current certificate of incorporation. The holders of redeemable convertible preferred stock and Class A Common Stock, voting together as a single class on an as-converted basis, were entitled to elect three mutual directors.

Redemption — The redeemable convertible preferred stock was recorded in mezzanine equity because while it was not mandatorily redeemable, it would have 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.

10. Derivative Tranche Liability

In connection with the Series C First Tranche Closing, prior to the IPO closing, the Company had an obligation to sell, and investors of the Series C First Tranche Closing had an obligation to purchase, an additional 12,228,881 shares of Series C redeemable convertible preferred stock at $ 12.2661 per share on June 30, 2023. The obligation of each investor to purchase shares at the Series C Second Tranche Closing were subject to the fulfillment, on or before such closing, of certain conditions including not closing the Company's first underwritten public offering of its Class A Common Stock under the Securities Act or the closing of a direct listing prior to June 30, 2023. The Series C Second Tranche Closing was terminated at the IPO closing, on May 9, 2023.

Prior to May 9, 2023, the obligation to issue and purchase shares was concluded to be a forward contract derivative liability and was measured at fair value using a probability weighted model at the issuance date. The initial fair value of the forward contract was $10.8 million and was recorded as a derivative tranche liability. The Company used the following assumptions to estimate the liability as of the issuance date: probability of achieving milestone of 90%; expected term equals the contractual term from September 2022 until June 2023; Series C preferred stock fair value of $ 12.2661; and a discount rate of 25%.

Following the termination of the Series C Second Tranche Closing at the closing of the IPO the Company recognized a gain on change in fair value of the derivative tranche liability in the amount of $10.3 million in the consolidated statements of operations and comprehensive loss for the year ended December 31, 2023.

11. Common Stock

On May 9, 2023, immediately prior to the IPO closing, each share of the Company's Class A Common Stock then issued and outstanding was reclassified and became one share of the Company's common stock. As of December 31, 2023 and 2022, there were no shares of Class B Common Stock outstanding.

As of December 31, 2023 and 2022, the Company's Common Stock reserved for future issuance was as follows:

	As of December 31,	
	2023	2022
Shares available for future grants under Equity Incentive Plan	3,526,392	1,570,353
Outstanding stock options	9,630,623	5,036,946
Performance-based restricted stock units	2,964,072	—
Outstanding restricted stock units	2,166,016	1,107,213
Options assumed upon ValenzaBio acquisition	938,440	—
ESPP Shares available for future grants	875,836	—
Redeemable convertible preferred stock	—	40,743,522
Total shares reserved for future issuance	20,101,379	48,458,034

Founders' Common Stock

On the IPO closing date, according to the terms of the restated certificate of incorporation, each share of the founders' Class A Common Stock issued and outstanding was reclassified and became 1 share of the Company's common stock; no vesting or other terms were modified.

In July 2020, the Company issued 2,839,749 shares of its common stock to founders at a price of $ 0.00002 per share. The issuance price was the estimated fair value of the shares as the 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 the right to repurchase unvested shares at the price paid by the founders if services are terminated. Stock-based compensation expense was minimal for these shares. In December 2022, the Company repurchased 591,613 restricted common shares at the original purchase price that were unvested as of the date of repurchase in connection with one founder's resignation. As of December 31, 2023 and 2022, 207,060 and 562,032 shares were unvested. During the years ended December 31, 2023 and 2022, 354,972 and 621,196 founders' shares vested, respectively.

12. Equity Incentive Plan

In April 2023, the Company's board of directors adopted, and stockholders approved, the 2023 Equity Incentive Plan (the "2023 Plan") that became effective on May 4, 2023. The Company reserved, 12,000,000 new shares of common stock for issuance under the 2023 Plan. In addition, 6,920,846 shares issued and outstanding under the Company's 2020 Equity Incentive Plan, as amended (the "2020 Plan"), have been added to the 2023 Plan as such shares become available from time to time if awards terminate, expire, or lapse for any reason without the delivery of shares, or are reacquired or withheld (or not issued) to satisfy a tax withholding obligation or the purchase or exercise price. The 2023 Plan also provides that the number of shares initially reserved and available for issuance will automatically increase each January 1, beginning on January 1, 2024 and ending on January 1, 2033, by an amount equal to the lesser of (i) 5% of the shares of common stock outstanding on the last day of the immediately preceding fiscal year, and (ii) such smaller number of shares of stock as determined by the Company's board of directors. No more than 56,762,538 shares of stock may be issued upon the exercise of incentive stock options under the 2023 Plan. The Company may grant incentive stock options, nonstatutory stock options ("NSOs"), restricted stock units ("RSUs"), restricted stock awards ("RSAs"), stock appreciation rights ("SARs"), performance awards and other awards to the Company's officers, employees, directors and consultants. Options under the 2023 Plan may be granted for periods of up to 10 years at exercise prices no less than the fair market value of the common stock on the date of grant and usually vest over four years. The exercise price of an option granted to a 10%

stockholder may not be less than 110% of the fair market value of the shares on the date of grant and such option may not be exercisable after the expiration of five years from the date of grant. The grant date fair market value of all awards made under our 2023 Plan and all cash compensation paid by us to any non-employee director for services as a director in any fiscal year may not exceed $750,000, increased to $1,000,000 in the fiscal year of their initial service as a non-employee director. The 2023 Plan is the successor to and continuation of the 2020 Plan and no additional awards may be granted under the 2020 Plan. All outstanding awards granted under the 2020 Plan will remain subject to the terms of the 2020 Plan. The 2020 Plan provided for the grant of incentive stock options, nonstatutory stock options, RSUs and RSAs to the Company's officers, employees, directors and consultants. As of December 31, 2023, 3,526,392 shares of the Company's common stock were reserved for issuance under the 2023 Plan.

In April 2023, the Company's board of directors and stockholders adopted the 2023 Employee Stock Purchase Plan (the "ESPP"), which became effective on May 4, 2023. The ESPP authorized issuance of up to 900,000 shares of common stock. The ESPP permits participants to purchase common stock through payroll deductions of up to 15% of their eligible compensation. Employees purchase shares of common stock at a price per share equal to 85% of the lower of the fair market value at the start or end of six-month purchase and offering consecutive periods. The aggregate number of shares reserved for sale under the 2023 ESPP will increase automatically on January 1 for a period of up to 10 calendar years, commencing on January 1, 2024, by the number of shares equal to the lesser of 1% of the Company's total outstanding shares of common stock on the immediately preceding December 31st, and 2,700,000 shares or a lesser number of shares as may be determined by the board of directors. There were 875,836 ESPP shares available for future grants as of December 31, 2023.

Stock Options

Stock options issued under the 2020 and 2023 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 and 2023 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 at December 31, 2022	5,036,946	$ 4.7872	9.5	$ 5,488
Options granted	6,196,917	$ 14.9001		
Options exercised	(330,506)	$ 5.1507		
Options expired	(10,653)	$ 18.0000		
Options forfeited	(1,262,081)	$ 10.9333		
Outstanding at December 31, 2023	9,630,623	$ 10.4619	9	$ 12,007
Exercisable at December 31, 2023	1,661,322	$ 4.4577	8.1	$ 5,226
Vested and expected to vest at December 31, 2023	9,630,623	$ 10.4619	9	$ 12,007

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, 2023 and 2022. Fair value of shares vested during the year ended December 31, 2023 was $10.6 million. The weighted-average grant date fair value of options granted in 2023 was $8.8732.

ValenzaBio 2020 Stock Option Plan

On January 4, 2023, in connection with the Acquisition, the Company assumed the ValenzaBio 2020 Stock Option Plan and options to issue 1,249,811 shares of the Company's Class A Common Stock to ValenzaBio option holders, who

entered into consulting agreements with the Company. The weighted-average exercise price of assumed options was $ 3.6736 per share.

Under the terms of the Merger Agreement, the assumed options vested in full on March 31, 2023. A total of 311,371 options assumed under the ValenzaBio 2020 Stock Option Plan having the weighted-average exercise price of $2.4921 were exercised for the year ended December 31, 2023.

The Company recognized the full amount of stock-based compensation expense of $ 4.9 million, including $3.1 million as research and development expenses and $1.8 million as general administrative expenses, related to assumed options in the consolidated statement of operations for the year ended December 31, 2023.

Restricted Stock Units

In 2022, the Company granted RSU awards for 1,107,213 shares vesting based on satisfaction of certain service and liquidity conditions. On March 23, 2023, the Board approved the acceleration of vesting of 138,401 RSUs. The Company accounted for the changes in vesting terms as a modification and re-measured modified awards at fair value on the modification date.

The estimated fair value of RSUs granted was $8.0 million after modification.

On May 9, 2023, the IPO closing date, 640,416 RSUs vested and the Company recognized $ 5.5 million stock-based compensation expense. The Company issued 303,237 shares and withheld 337,179 shares to satisfy tax withholding obligations of $ 8.3 million paid upon the RSU settlement.

On August 16, 2023, the company granted 1,725,168 RSUs shares to certain employees of the Company, which shall vest in four equal installments beginning on May 15, 2024, subject to the employee's continuous service through each applicable vesting date, and the Company recognized $5.8 million stock-based compensation expense in relation with these awards for the year ended December 31, 2023.

Remaining unvested RSUs were 2,166,016 as of December 31, 2023.

A summary of unvested RSU activity is presented in the following table:

	Number of RSUs	Weighted-Average Grant Date Fair Value
Unvested at December 31, 2022	1,107,213	$ 5.42
Granted	1,725,168	28.15
Vested	(640,416)	6.65
Forfeited	(25,949)	26.97
Unvested at December 31, 2023	2,166,016	$ 22.90

Performance-Based Restricted Stock Units

In August 2023, the Company granted PSUs to certain employees and officers of the Company. The PSUs may vest over several years subject to the achievement of (i) certain clinical development milestones over a performance period from the grant date to May 2027 (the "Performance Period") or (ii) market conditions (i.e., stock price hurdle) based on pre-specified volume-weighted average stock price measurements as of each vesting performance measurement date, and continued employment with the Company through the applicable vesting date(s). The target number of shares under the PSUs is 3,135,104. The ultimate number of PSU shares that may vest, in the aggregate over the Performance Period, could in certain cases be up to 150% of the target number of shares upon the achievement of certain market or performance conditions.

A summary of PSU activity based on the target number of shares is presented in the following table:

	Number of PSUs	Weighted-Average Grant Date Fair Value*
Outstanding at December 31, 2022	—	$ —
Granted	3,135,104	27.43
Vested	—	—
Forfeited	(171,032)	27.43
Outstanding at December 31, 2023	2,964,072	$ 27.43

*The grant date fair value is based only on the PSUs with market conditions and does not factor in any performance conditions.

As the PSUs granted in 2023 are subject to a market condition, the grant date fair value for such PSUs was based on a Monte Carlo simulation model. The Company estimated the fair value of PSUs based on the grant date price of its common stock of $26.97 and the following assumptions: expected volatility of 87.71%, risk-free-rate of 4.47%, and zero expected dividend yield. In 2023, the Company granted PSUs to employees with a weighted-average grant date fair value of $27.43. The unvested awards will expire if it is determined that the vesting conditions have not been met during the applicable three-year performance period.

2023 Employee Stock Purchase Plan

The first purchase period commenced on June 15, 2023 and ended on December 14, 2023. The Company recorded less than $ 0.1 million in accrued liabilities as of December 31, 2023. During the year ended December 31, 2023, the Company's employees purchased a total of 24,164 shares under the 2023 ESPP at a total purchase price of $0.1 million.

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.* Prior to the Company's IPO, 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 the Company's 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.

  For valuations performed after December 31, 2021 in accordance with the Practice Aid the Company utilized the hybrid method for determining the fair value of our Class A Common Stock based on the Company's

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 was then applied to arrive at an indication of value for the Class A Common Stock.

The Company also considered the amount of time between the independent third-party valuation dates and the grant date of an award. The Company interpolated the common stock fair value between the two valuation dates, if there were 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.

Following the Company's IPO, the fair market value of the Company's common stock is based on its closing price on Nasdaq as reported on the date of the stock option grant.

- *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.* The expected volatility is 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 as the Company does not have sufficient trading history for its publicly traded common stock. 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 to estimate fair value of each option at the grant date for the years ended December 31, 2023, 2022 and 2021:

	Year Ended December 31,		
	2023	**2022**	**2021**
Expected volatility	85.17% - 94.74%	96.33% - 102.81%	99.97% - 100.78%
Expected dividend yield	0 %	0 %	0 %
Expected term (in years)	5.77 - 6.08 years	5.88 - 6.08 years	5.93 - 6.06 years
Risk-free interest rate	3.30% - 4.80%	1.69% - 3.96%	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,		
	2023	2022	2021
Research and development expenses	$ 12,652	$ 1,373	$ 214
General and administrative expenses	34,666	2,679	19
Total stock-based compensation expense	$ 47,318	$ 4,052	$ 233

The stock-based compensation expense relates to the following equity-based awards:

	Year Ended December 31,		
	2023	2022	2021
Restricted stock units	$ 11,726	$ —	$ —
Performance-based restricted stock units	12,109	—	—
Stock options	23,281	2,035	233
ESPP	202	—	—
Restricted stock awards	—	2,017	—
Total stock-based compensation expense	$ 47,318	$ 4,052	$ 233

The Company recognized $4.9 million stock-based compensation expense related to assumed ValenzaBio options and $ 0.9 million related to unvested options and RSAs net-settled at the closing of the Acquisition. As of December 31, 2023, there was $65.5 million of unrecognized stock-based compensation expense related to granted stock options, which is expected to be recognized over a weighted-average period of 3.2 years. As of December 31, 2023, there was $41.7 million of unrecognized stock-based compensation expense related to RSUs which will be recognized over the remaining vesting term through May 2027. The Company recognized $12.1 million in compensation expense during the year ended December 31, 2023 related to PSUs. This expense is related only to the market conditions associated with the PSUs. As of December 31, 2023, the Company evaluated the clinical development milestone performance conditions and determined them to be not probable of achievement. As of December 31, 2023, total compensation cost not yet recognized related to unvested PSUs was $65.4 million, which is expected to be recognized over a weighted-average period of 2.3 years. Total compensation cost not recognized related to unvested PSUs can increase up to $ 86.6 million depending on the future achievement of PSUs performance conditions.

13. Related Party Transactions

During the years ended December 31, 2023, and 2021 the Company did not enter into transactions with related parties outside of the ordinary course of the business. During the year ended December 31, 2022, the Company paid $10,000 to one of the stockholders as a reimbursement of Series B Stock issuance costs.

14. 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,		
	2023	2022	2021
Numerator:			
Net loss	$ (381,641)	$ (64,772)	$ (41,839)
Denominator:			
Weighted average common shares outstanding	70,647,093	3,271,978	2,843,305
Less: Weighted-average common shares subject to repurchase	(397,513)	(1,714,444)	(2,155,907)
Weighted-average common shares outstanding, basic and diluted	70,249,580	1,557,534	687,398
Net loss per share attributable to common stockholders, basic and diluted	$ (5.43)	$ (41.59)	$ (60.87)

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,		
	2023	2022	2021
Outstanding options to purchase common stock	9,630,623	5,036,946	481,994
Unvested RSUs outstanding	2,166,016	1,107,213	—
Outstanding options to purchase common stock assumed upon the ValenzaBio acquisition	938,440	—	—
Common stock subject to repurchase	207,060	562,032	1,774,841
ESPP	87,356	—	—
Redeemable convertible preferred stock	—	40,743,522	16,285,718
Total	13,029,495	47,449,713	18,542,553

The table above does not include contingently issuable PSUs with market or performance vesting conditions, given as of December 31, 2023, the performance conditions were not deemed probable to be achieved (see Note 12).

15. Income Taxes

No provision for income taxes was recorded for the year ended December 31, 2023, 2022 and 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,		
	2023	2022	2021
Income tax computed at federal statutory rate	21.00 %	21.00 %	21 %
State taxes	0.07	0.71	0.26
Other permanent differences	(1.03)	(0.43)	(0.11)
Research credits	1.12	1.40	0.19
Change in valuation allowance	(14.38)	(22.68)	(21.34)
IPR&D	(6.78 %)	— %	— %
Effective income tax rate	— %	— %	— %

Significant components of the deferred tax assets and liabilities were as follows (in thousands):

	Year Ended December 31,	
	2023	2022
Deferred Tax Assets:		
Net operating loss carry forwards	$ 19,640	$ 6,203
Capitalized R&E expenditures	52,911	10,814
Intangibles	14,439	4,785
Research credits	6,898	1,259
Lease liability	298	—
Other	4,782	676
Total deferred tax assets	98,968	23,737
Less: Valuation allowance	(98,716)	(23,737)
Net deferred tax assets	$ 252	$ —
Right-of-use asset (ROU)	$ (252)	$ —
Net deferred tax liability	$ (252)	$ —
Total net deferred tax assets	$ —	$ —

Beginning January 1, 2022, the Tax Cuts and Jobs Act, or the Tax Act, eliminated the option to deduct research and development expenditures in the current year and requires taxpayers to capitalize such expenses pursuant to Internal Revenue Code Section 174. The capitalized expenses are amortized over a 5-year period for domestic expenses and a 15-year period for foreign expenses.

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 balance of the valuation allowance was less than $0.1 million beginning January 1, 2021. The valuation allowance increased by $75.0 million, $14.7 million, and $8.9 million, for the years ended December 31, 2023 and 2022 and 2021, respectively, primarily due to changes in capitalized R&D expenditures, net operating loss carry forwards, research and development credits, and capitalization of certain intangibles.

The following table sets forth the Company's federal and state net operating loss carryforwards and tax credits as of December 31, 2023 (dollars in thousands):

	Amount	Begin to Expire
Net operating losses, Federal	$ 92,703	Do not expire
Net operating losses, State	$ 6,820	2041
Tax credits, Federal	$ 8,320	2041
Tax credits, California	$ 1,110	Do not expire

Federal and state laws impose substantial restrictions on the utilization of net operating loss and tax credit carryforwards in the event of an ownership change for tax purposes, as defined in Section 382 of the Internal Revenue Code. As a result of such ownership changes, the annual limitation may result in the expiration of net operating losses and credits before utilization. The Company has experienced ownership changes in the past and in the current year. We completed a Section 382 analysis through December 31, 2023, and concluded that although an ownership change had occurred, the Company's net operating losses and credits were substantially free of limitations as of December 31, 2023.

Uncertain Tax Positions

A reconciliation of the beginning and ending balances of the unrecognized tax benefits during the year ended December 31, 2023, 2022 and 2021 are as follows (in thousands)

	Year Ended December 31,		
	2023	2022	2021
Beginning balance	$ 516	$ 48	$ —
Increase in tax positions in the current period	1,600	468	48
Additions for tax positions of prior years	233	—	—
Ending balance	$ 2,348	$ 516	$ 48

The entire amount of the unrecognized tax benefits would not impact the Company's effective tax rate if recognized. The Company has elected to include interest and penalties as a component of tax expense. The Company determined that no accrual for interest and penalties related to unrecognized tax benefits was required as of December 31, 2023, 2022 and 2021. The Company does not anticipate that the amount of existing unrecognized tax benefits will significantly increase or decrease during the next 12 months.

The Company is subject to examination by the U.S. federal and state tax authorities from inception to December 31, 2023. 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.

16. Subsequent Events

In November 2023, we disclosed a vendor programming error caused a dose-sequencing error in the 160 mg every other week and 80mg every four weeks dosing arms of our Phase 2b/3 trial in Psoriatic Arthritis. In connection with this error, on March 10, 2024, we entered into arrangements with certain vendors that enabled a multi-party solution where we have received in the first quarter of 2024, a payment of $30.0 million and a $5 million service credit.

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosures

None

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation and supervision of our Chief Executive Officer and our Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2023, the end of the period covered by this Annual Report on Form 10-K. Disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) are designed to provide reasonable assurance that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to a company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure.

Based on their evaluation, the Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were not effective as of December 31, 2023 because of the material weaknesses in our internal control over financial reporting described below.

Management's Annual Report on Internal Control over Financial Reporting

This Annual Report does not include a report of management's assessment regarding internal control over financial reporting due to a transition period established by the rules of the SEC for newly public companies.

Attestation Report of the Registered Public Accounting Firm

This Annual Report does not include an attestation report of our registered public accounting firm due to an exemption provided by the JOBS Act for "emerging growth companies."

Material Weaknesses in 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 annual or interim financial statements will not be prevented or detected on a timely basis.

As of December 31, 2023, we concluded the following material weaknesses exist:

- 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.

Remediation Plan and Status

During the year ended December 31, 2023, our management, with the oversight of the Audit Committee of our Board of Directors, designed and implemented measures to remediate the control deficiencies contributing to the material weaknesses. These remediation efforts include the following:

- We designed and implemented a comprehensive risk assessment process to identify and design our control activities related to the above-mentioned material weaknesses. In addition, we continue to assess risks on a continuous basis to timely identify new exposures or risk categories as business practices change and, as applicable, update our existing internal control framework to ensure that it has identified, developed and deployed the appropriate business process controls to meet the objectives and address the risks identified.
- We designed and implemented preventive and detective controls over the segregation of duties related to journal entries and account reconciliations. Specifically, we restricted the ability for one individual to both (i) create and post a journal entry in the general ledger and (ii) prepare and review account reconciliations.

We have designed and implemented the controls necessary to remediate the material weaknesses related to the company's risk assessment process and segregation of duties related to journal entries and account reconciliations; however, we have determined that certain controls have not operated for a sufficient period of time to fully conclude remediation of the two material weaknesses as of December 31, 2023. We believe the measures described above and upon completion of further operation and testing of the required controls will remediate the two unremediated material weaknesses and strengthen our internal control over financial reporting.

Remediation of Prior Material Weakness

We previously 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. Through our hiring of necessary personnel and testing of related internal controls for design and operating effectiveness, we have determined that the material weakness related to insufficient accounting personnel was remediated as of December 31, 2023.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended December 31, 2023, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on the Effectiveness of Controls

In designing and evaluating the disclosure controls and procedures, management recognizes that because of the inherent limitations in all control systems, any controls and procedures, no matter how well designed and operated, can provide only reasonable not absolute, assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and the benefits of controls and procedures must be considered relative to their costs.

Item 9B. Other Information

None

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspection

None

PART III

Item 10. Directors, Executive Officers and Corporate Governance

Our Code of Business Conduct and Ethics applies to all of 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 may be viewed on the investors relations portion of our website at investors.acelyrin.com, in the section titled "Corporate Governance." We intend to satisfy the disclosure requirements under Item 5.05 of the SEC Form 8-K regarding an amendment to, or waiver from, a provision of our Code of Business Conduct and Ethics by posting such information on our website, at the website address and location specified above.

Other information required by this Item will be included in the Company's definitive proxy statement to be filed with the SEC within 120 days after December 31, 2023, in connection with the solicitation of proxies for the Company's 2024 annual meeting of shareholders (the "2024 Proxy Statement"), and is incorporated herein by reference.

Item 11. Executive Compensation

The information required by this Item will be included in the 2024 Proxy Statement, and is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owner and Management and Related Stockholder Matters

The information required by this Item will be included in the 2024 Proxy Statement, and is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The information required by this Item will be included in the 2024 Proxy Statement, and is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services

The information required by this Item will be included in the 2024 Proxy Statement, and is incorporated herein by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules

(a) We have filed the following documents as part of this Annual Report:

(1) Consolidated Financial Statements

Information in response to this Item is included in Part II, Item 8 of this Annual Report.

(2) Financial Statement Schedules

All financial statement schedules have been omitted, since the required information is not applicable or is not present in amounts sufficient to require submission of the schedule, or because the information required is included in the consolidated financial statements and accompanying notes included in this Form 10-K.

(b) Exhibits

Exhibit Number	Description	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
2.1	Agreement and Plan of Merger and Reorganization by and among the Registrant, ValenzaBio, Inc., WH1, INC., WH2, LLC and Seller Representatives LLC dated December 20, 2022.	S-1/A	333-271244	2.1	May 3, 2023
3.1	Amended and Restated Certificate of Incorporation of the Company.	8-K	001-41696	3.1	May 9, 2023
3.2	Amended and Restated Bylaws of the Registrant.	8-K	001-41696	3.2	May 9, 2023
4.1	Form of Common Stock Certificate of the Registrant.	S-1/A	333-271244	4.1	May 3, 2023
4.2	Amended and Restated Investors' Rights Agreement, by and among the Registrant and certain of its stockholders, dated September 9, 2022.	S-1/A	333-271244	4.2	May 3, 2023
4.3*	Description of the Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934				
10.1	ACELYRIN, INC. 2020 Stock Option and Grant Plan, as amended.	S-1/A	333-271244	10.1	May 3, 2023
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.	S-1/A	333-271244	10.2	May 3, 2023
10.3	ACELYRIN, INC. 2023 Equity Incentive Plan.	S-1/A	333-271244	10.3	May 3, 2023
10.4	Forms of Stock Option Grant Notice, Stock Option Agreement and Notice of Exercise under the ACELYRIN, INC. 2023 Equity Incentive Plan.	S-1/A	333-271244	10.4	May 3, 2023
10.5	Forms of Restricted Stock Unit Grant Notice and Award Agreement under the ACELYRIN, INC. 2023 Equity Incentive Plan.	S-1/A	333-271244	10.5	May 3, 2023
10.6	ACELYRIN, INC. 2023 Employee Stock Purchase Plan.	S-1/A	333-271244	10.6	May 3, 2023
10.7	ValenzaBio, Inc. Stock Plan and forms thereunder.	S-1/A	333-271244	10.7	May 3, 2023
10.8	ACELYRIN, INC. 2023 Non-Employee Director Compensation Policy.	S-1/A	333-271244	10.8	May 3, 2023
10.9	ACELYRIN, INC. Severance Plan.	S-1/A	333-271244	10.9	May 3, 2023
10.10	Form of Indemnification Agreement by and between the Registrant and its directors and executive officers.	S-1/A	333-271244	10.10	May 3, 2023
10.11	Form of Employment Agreement for Executive Officers.	S-1/A	333-271244	10.11	May 3, 2023

Exhibit Number	Description	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
10.12	License and Collaboration Agreement by and between the Registrant and Affibody AB, dated August 9, 2021, as amended.	S-1/A	333-271244	10.12	May 3, 2023
10.13	License and Commercialization Agreement by and between ValenzaBio Inc. and Pierre Fabre Medicament SAS, dated March 25, 2021, as amended.	S-1/A	333-271244	10.13	May 3, 2023
10.14	ACELYRIN, INC. Cash Incentive Plan.	S-1/A	333-271244	10.14	May 3, 2023
10.15	Separation Agreement and Release by and between Mardi C. Dier and the Company	8-K	001-41696	10.1	August 2, 2023
21.1	List of Subsidiaries.	S-1/A	333-271244	21.1	May 3, 2023
23.1*	Consent of PricewaterhouseCoopers LLP, independent registered public accounting firm of ACELYRIN, INC.				
24.1*	Power of Attorney (included on signature page).				
31.1*	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
31.2*	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
32.1*+	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
97.1*	Incentive Compensation Recoupment Policy				
101.ins*	Instance Document				
101.sch*	Inline XBRL Taxonomy Extension Schema Document				
101.cal*	Inline XBRL Taxonomy Extension Calculation Linkbase Document				
101.def*	Inline XBRL Taxonomy Extension Definition Linkbase Document				
101.lab*	Inline XBRL Taxonomy Extension Label Linkbase Document				
101.pre*	Inline XBRL Taxonomy Extension Presentation Linkbase Document				
104*	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101)				

* Filed herewith.

\+ Furnished herewith and not deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended.

(c) 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 16. Form 10-K Summary

None

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Act of 1934, as amended, the registrant has duly caused this Annual Report to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Agoura Hills, California on March 28, 2024.

ACELYRIN, INC.

By:	/s/ Shao-Lee Lin
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 each of Shao-Lee Lin and Gil M. Labrucherie his or her true and lawful attorney-in-fact and agent, with full power of substitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent, 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 or she might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or his or her substitutes or substitute, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1934, this report has been signed by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Shao-Lee Lin Shao-Lee Lin, M.D., Ph.D.	Founder, Chief Executive Officer and Director *(Principal Executive Officer)*	March 28, 2024
/s/ Gil M. Labrucherie Gil M. Labrucherie	Chief Financial Officer *(Principal Financial and Accounting Officer)*	March 28, 2024
/s/ Bruce C. Cozadd Bruce C. Cozadd	Director	March 28, 2024
/s/ Dan Becker Dan Becker, M.D., Ph.D.	Director	March 28, 2024
/s/ Alan B. Colowick Alan B. Colowick, M.D., M.P.H.	Director	March 28, 2024
/s/ Henry O. Gosebruch Henry O. Gosebruch	Director	March 28, 2024
/s/ Patrick Machado Patrick Machado, J.D.	Director	March 28, 2024
/s/ Beth Seidenberg Beth Seidenberg, M.D.	Director	March 28, 2024
/s/ Dawn Svoronos Dawn Svoronos	Director	March 28, 2024
/s/ Lynn Tetrault Lynn Tetrault	Director	March 28, 2024

Exhibit 4.3

DESCRIPTION OF THE REGISTRANT'S SECURITIES
REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

The following is a description of the common stock, $0.00001 par value per share ("Common Stock") of ACELYRIN, INC. (the "Company," "we," "our", or "us") which is the only security of the Company registered pursuant to Section 12 of the Securities Exchange Act of 1934, as amended. The following summary description is based on the provisions of our Amended and Restated Certificate of Incorporation (the "Restated Certificate"), our Amended and Restated Bylaws, (the "Bylaws"), and the applicable provisions of the Delaware General Corporation Law (the "DGCL"). This information may not be complete in all respects and is qualified entirely by reference to the provisions of our Restated Certificate and our Bylaws. Our Restated Certificate and our Bylaws are filed as exhibits to our Annual Report on Form 10-K of which this exhibit is a part.

Authorized Capital Shares

Our authorized capital stock consists of 790,000,000 shares of common stock, par value $0.00001 per share and 10,000,000 shares of preferred stock, par value $0.00001 per share, all of which are undesignated.

Common Stock

Voting Rights

The common stock is entitled to one vote per share on any matter that is submitted to a vote of our stockholders provided, however, that, except as otherwise required by applicable law, holders of Common Stock shall not be entitled to vote on any amendment to this Certificate of Incorporation (including any certificate of designation filed with respect to any series of Preferred Stock) that relates solely to the terms of one or more outstanding series of Preferred Stock if the holders of such affected series of Preferred Stock are entitled, either separately or together as a class with the holders of one or more other such series of Preferred Stock, to vote thereon pursuant to applicable law or the Certificate of Incorporation (including any certificate of designation filed with respect to any series of Preferred Stock). Our Restated Certificate does not provide for cumulative voting for the election of directors. Our Restated Certificate establishes a classified board of directors that is divided into three classes with staggered three-year terms. Only the directors in one class will be subject to election by a plurality of the votes cast at each annual meeting of our stockholders, with the directors in the other classes continuing for the remainder of their respective three-year terms. The affirmative vote of holders of at least 66 2/3% of the voting power of all of the then-outstanding shares of capital stock, voting as a single class, will be required to amend certain provisions of our Restated Certificate, including provisions relating to amending our Bylaws, the classified structure of our board of directors, the size of our board of directors, removal of directors, director liability, vacancies on our board of directors, special meetings, stockholder notices, actions by written consent and exclusive jurisdiction.

Economic Rights

Except as otherwise expressly provided in our Restated Certificate or required by applicable law, all shares of common stock 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 apply to any shares of preferred stock outstanding at the time, the holders of our common stock are entitled to receive dividends out of funds legally available if our board

of directors, in its discretion, determines to issue dividends and then only at the times and in the amounts that our board of directors may determine.

Liquidation Rights. On our liquidation, dissolution, or winding-up, the holders of common stock will be entitled to share equally, identically and ratably in all assets remaining after the payment of any liabilities, liquidation preferences and accrued or declared but unpaid dividends, if any, with respect to any outstanding preferred stock, unless a different treatment is approved by the affirmative vote of the holders of a majority of the outstanding shares of such affected class, voting separately as a class.

No Preemptive or Similar Rights

The holders of our shares of common stock are not entitled to preemptive rights, and are not subject to conversion, redemption or sinking fund provisions.

Preferred Stock

Our board of directors may, without further action by our stockholders, fix the rights, preferences, privileges and restrictions of up to 10,000,000 shares of preferred stock in one or more series and authorize their issuance, establish from time to time the number of shares to be included in each such series and increase or decrease the number of shares of any such series, but not below the number of shares of such series then outstanding. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences and the number of shares constituting any series or the designation of such series, any or all of which may be greater than the rights of common stock. Any issuance of preferred stock could adversely affect the voting power of holders of common stock and the likelihood that such holders would receive dividend payments and payments on liquidation. In addition, the issuance of preferred stock could have the effect of delaying, deterring or preventing a change of control or other corporate action.

Anti-Takeover Provisions

The provisions of Delaware law, our Restated Certificate and our Bylaws, which are summarized below, may have the effect of delaying, deferring or discouraging another person from acquiring control of our company. They are also designed, in part, to encourage persons seeking to acquire control of us to negotiate first with our board of directors. We believe that the benefits of increased protection of our potential ability to negotiate with an unfriendly or unsolicited acquirer outweigh the disadvantages of discouraging a proposal to acquire us because negotiation of these proposals could result in an improvement of their terms.

Restated Certificate and Bylaws

Because our stockholders do not have cumulative voting rights, stockholders holding a majority of the voting power of our shares of common stock are able to elect all of our directors. Our Restated Certificate also provides that all stockholder actions are required to be taken by a vote of the stockholders at an annual or special meeting, and that stockholders may not take any action by written consent in lieu of a meeting.. According to our Bylaws, a special meeting of stockholders may only be called by a majority of our board of directors, the chair of our board of directors, or our chief executive officer. Our Bylaws establish an advance notice procedure for stockholder proposals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors.

Our Restated Certificate provides for the division of our board of directors into three classes serving staggered three-year terms, with one class being elected each year. Our Restated Certificate also provides that directors may be removed only for cause by the affirmative vote of the holders of at least 66 2/3% of the shares then entitled to vote at an annual election of directors. Furthermore, any vacancy on our board of

directors, however occurring, including a vacancy resulting from an increase in the size of our board, may be filled by the affirmative vote of a majority of our directors then in office even if less than a quorum.

The foregoing provisions make it more difficult 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 designed to reduce our vulnerability to an unsolicited acquisition proposal 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 deterring hostile takeovers or 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.

Section 203 of the Delaware General Corporation Law

We are subject to the provisions of Section 203 of the Delaware General Corporation Law, or Section 203. In general, Section 203 prohibits a publicly-held 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, subject to certain exceptions. A "business combination" includes, among other things, a merger, asset or stock sale or other transaction resulting in a financial benefit to the interested stockholder. An "interested stockholder" is a person who, together with affiliates and associates, owns, or did own within three years prior to the determination of interested stockholder status, 15% or more of the corporation's voting stock.

Choice of Forum

Our Restated Certificate provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if and only if the Court of Chancery of the State of Delaware lacks subject matter jurisdiction, any state court located within the State of Delaware or, if and only if all such state courts lack subject matter jurisdiction, the federal district court for the District of Delaware) and any appellate court therefrom is the sole and exclusive forum for the following claims or causes of action under the Delaware statutory or common law: (i) any derivative claim or cause of action brought on our behalf; (ii) any claim or cause of action for a breach of fiduciary duty owed by any of our current or former directors, officers or other employees to us or our stockholders; (iii) any claim or cause of action against us or any of our current or former directors, officers or other employees arising out of or pursuant to any provision of the DGCL, our Restated Certificate or our Bylaws (as each may be amended from time to time); (iv) any claim or cause of action seeking to interpret, apply, enforce or determine the validity of our Restated Certificate or our Bylaws (as each may be amended from time to time, including any right, obligation, or remedy thereunder); (v) any claim or cause of action as to which the DGCL confers jurisdiction to the Court of Chancery of the State of Delaware; and (vi) any claim or cause of action against us or any of our current or former directors, officers or other employees governed by the internal-affairs doctrine, in all cases to the fullest extent permitted by law and subject to the court's having personal jurisdiction over the indispensable parties named as defendants. Our Restated Certificate further provides that, unless we consent in writing to the selection of an alternative forum, to the fullest extent permitted by law, the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause or causes of action arising under the Securities Act, including all causes of action asserted against an defendant to such complaint. The choice of forum provisions would not apply to claims or causes

of action brought to enforce a duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction.

For the avoidance of doubt, these provisions are 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. 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, and there can be no assurance that such provisions will be enforced by a court in those other jurisdictions. We note that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder.

Additionally, our Restated Certificate provides that any person or entity holding, owning or otherwise acquiring any interest in any of our securities shall be deemed to have notice of and consented to these provisions. These 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, other employees or stockholders, which may discourage lawsuits with respect to such claims, although our stockholders will not be deemed to have waived our compliance with federal securities laws and the rules and regulations thereunder.

Limitations on Liability and Indemnification

Our Restated Certificate contains provisions that limit the liability of our directors for monetary damages to the fullest extent permitted by Delaware law. Consequently, our directors will not be personally liable to us or our stockholders for monetary damages for any breach of fiduciary duties as directors, except liability for:

- any breach of the director's duty of loyalty to us or our stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- unlawful payments of dividends or unlawful stock repurchases or redemptions; or
- any transaction from which the director 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 Restated Certificate authorizes us to indemnify our directors, officers, employees and other agents to the fullest extent permitted by Delaware law. Our Bylaws provide that we are required to indemnify our directors and officers, in each case to the fullest extent permitted by Delaware law and may indemnify our other employees and agents. Our Bylaws also obligate us to 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 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 our board of directors. With specified exceptions, these agreements provide for indemnification for related expenses including, among other things, attorneys' fees, judgments, fines and settlement amounts incurred by any of these individuals in any action or proceeding. We believe that these 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 Restated Certificate and Bylaws may discourage stockholders from bringing a lawsuit against our directors and officers 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 our stockholders. Further, a stockholder's investment may be adversely affected to the extent that we pay the costs of settlement and damages.

Exchange Listing

Our common stock listed on The Nasdaq Global Select Market under the symbol "SLRN."

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Computershare Trust Company, N.A. The transfer agent's address is 150 Royall Street, Canton, MA 02021.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statement on Form S-8 (No. 333-271737) of ACELYRIN, INC. of our report dated March 28, 2024 relating to the financial statements, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP

San Diego, California March 28, 2024

Exhibit 31.1

CERTIFICATION PURSUANT TO RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Shao-Lee Lin, M.D., Ph. D., certify that

1. I have reviewed this Annual Report on Form 10-K of ACELYRIN, INC.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    c. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting

March 28, 2024

By: /s/ Shao-Lee Lin
Shao-Lee Lin, M.D., Ph.D.
Chief Executive Officer

Exhibit 31.2

CERTIFICATION PURSUANT TO RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Gil M. Labrucherie, certify that

1. I have reviewed this Annual Report on Form 10-K of ACELYRIN, INC.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    c. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting

March 28, 2024

By: */s/ Gil M. Labrucherie*
Gil M. Labrucherie
Chief Financial Officer

Exhibit 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Shao-Lee Lin, Chief Executive Officer of ACELYRIN, INC. (the "Company"), and Gil M. Labrucherie, Chief Financial Officer of the Company, each hereby certifies that, to the best of her or his knowledge:

i. the Annual Report on Form 10-K of the Company for the period ended December 31, 2023, to which this Certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Exchange Act; and

ii. the information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 28, 2024

/s/ Shao-Lee Lin	/s/ Gil M. Labrucherie
Shao-Lee Lin, M.D., Ph.D.	Gil M. Labrucherie
Chief Executive Officer	Chief Financial Officer

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of ACELYRIN, INC. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.

Exhibit 97.1

ACELYRIN, INC.

INCENTIVE COMPENSATION RECOUPMENT POLICY

1. INTRODUCTION

The Board of Directors (the "***Board***") of ACELYRIN, Inc., a Delaware corporation (the "***Company***"), has determined that it is in the best interests of the Company and its stockholders to adopt this Incentive Compensation Recoupment Policy (this "***Policy***") providing for the Company's recoupment of Recoverable Incentive Compensation that is received by Covered Officers of the Company under certain circumstances. Certain capitalized terms used in this Policy have the meanings given to such terms in Section 3 below.

This Policy is designed to comply with, and shall be interpreted to be consistent with, Section 10D of the Exchange Act, Rule 10D-1 promulgated thereunder ("***Rule 10D-1***") and Nasdaq Listing Rule 5608 (the "***Listing Standards***").

2. EFFECTIVE DATE

This Policy shall apply to all Incentive Compensation that is received by a Covered Officer on or after October 2, 2023 (the "***Effective Date***"). Incentive Compensation is deemed "***received***" in the Company's fiscal period in which the Financial Reporting Measure specified in the Incentive Compensation award is attained, even if the payment or grant of such Incentive Compensation occurs after the end of that period.

3. DEFINITIONS

"***Accounting Restatement***" means an accounting restatement that the Company is required to prepare due to the material noncompliance of the Company with any financial reporting requirement under the securities laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements, or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period.

"***Accounting Restatement Date***" means the earlier to occur of (a) the date that the Board, a committee of the Board authorized to take such action, or the officer or officers of the Company authorized to take such action if Board action is not required, concludes, or reasonably should have concluded, that the Company is required to prepare an Accounting Restatement, or (b) the date that a court, regulator or other legally authorized body directs the Company to prepare an Accounting Restatement.

"***Administrator***" means the Compensation Committee or, in the absence of such committee, the Board.

"***Code***" means the U.S. Internal Revenue Code of 1986, as amended, and the regulations promulgated thereunder.

"***Compensation Committee***" means the Compensation Committee of the Board.

"***Covered Officer***" means each current and former Executive Officer.

"***Exchange***" means the Nasdaq Stock Market.

"***Exchange Act***" means the U.S. Securities Exchange Act of 1934, as amended.

"***Executive Officer***" means the Company's president, principal financial officer, principal accounting officer (or if there is no such accounting officer, the controller), any vice-president of the Company in charge of a principal business unit, division, or function (such as sales, administration, or finance), any other officer who performs a policy-making function, or any other person who performs similar policy-making functions for the Company. Executive officers of the Company's parent(s) or subsidiaries are deemed executive officers of the Company if they perform such policy-making functions for the Company. Policy-making function is not intended to include policy-making functions that are not significant. Identification of an executive officer for purposes of this Policy would include at a minimum executive officers identified pursuant to Item 401(b) of Regulation S-K promulgated under the Exchange Act.

"***Financial Reporting Measures***" means measures that are determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, and any measures derived wholly or in part from such measures, including Company stock price and total stockholder return ("***TSR***"). A measure need not be presented in the Company's financial statements or included in a filing with the SEC in order to be a Financial Reporting Measure.

"***Incentive Compensation***" means any compensation that is granted, earned or vested based wholly or in part upon the attainment of a Financial Reporting Measure.

"***Lookback Period***" means the three completed fiscal years immediately preceding the Accounting Restatement Date, as well as any transition period (resulting from a change in the Company's fiscal year) within or immediately following those three completed fiscal years (except that a transition period of at least nine months shall count as a completed fiscal year). Notwithstanding the foregoing, the Lookback Period shall not include fiscal years completed prior to the Effective Date.

"***Recoverable Incentive Compensation***" means Incentive Compensation received by a Covered Officer during the Lookback Period that exceeds the amount of Incentive Compensation that would have been received had such amount been determined based on the Accounting Restatement, computed without regard to any taxes paid (*i.e.*, on a gross basis without regard to tax withholdings and other deductions). For any compensation plans or programs that take into account Incentive Compensation, the amount of Recoverable Incentive Compensation for purposes of this Policy shall include, without limitation, the amount contributed to any notional account based on Recoverable Incentive Compensation and any earnings to date on that notional amount. For any Incentive Compensation that is based on stock price or TSR, where the Recoverable Incentive Compensation is not subject to mathematical recalculation directly from the information in an Accounting Restatement, the Administrator will determine the amount of Recoverable Incentive Compensation based on a reasonable estimate of the effect of the Accounting Restatement on the stock price or TSR upon which the Incentive Compensation was received. The Company shall maintain documentation of the determination of that reasonable estimate and provide such documentation to the Exchange in accordance with the Listing Standards.

"***SEC***" means the U.S. Securities and Exchange Commission.

4. RECOUPMENT

(a) Applicability of Policy. This Policy applies to Incentive Compensation received by a Covered Officer (i) after beginning services as an Executive Officer, (ii) who served as an Executive Officer at any time during the performance period for such Incentive Compensation, (iii) while the Company had a class of securities listed on a national securities exchange or a national securities association, and (iv) during the Lookback Period.

(b) Recoupment Generally. Pursuant to the provisions of this Policy, if there is an

Accounting Restatement, the Company must reasonably promptly recoup the full amount of the Recoverable Incentive Compensation, unless the conditions of one or more subsections of Section 4(c) of this Policy are met and the Compensation Committee, or, if such committee does not consist solely of independent directors, a majority of the independent directors serving on the Board, has made a determination that recoupment would be impracticable. Recoupment is required regardless of whether the Covered Officer engaged in any misconduct and regardless of fault, and the Company's obligation to recoup Recoverable Incentive Compensation is not dependent on whether or when any restated financial statements are filed.

(c) Impracticability of Recovery. Recoupment may be determined to be impracticable if, and only if:

(i) the direct expense paid to a third party to assist in enforcing this Policy would exceed the amount of the applicable Recoverable Incentive Compensation; provided that, before concluding that it would be impracticable to recover any amount of Recoverable Incentive Compensation based on expense of enforcement, the Company shall make a reasonable attempt to recover such Recoverable Incentive Compensation, document such reasonable attempt(s) to recover, and provide that documentation to the Exchange in accordance with the Listing Standards; or

(ii) recoupment of the applicable Recoverable Incentive Compensation would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of the Company, to fail to meet the requirements of Code Section 401(a)(13) or Code Section 411(a) and regulations thereunder.

(d) Sources of Recoupment. To the extent permitted by applicable law, the Administrator shall, in its sole discretion, determine the timing and method for recouping Recoverable Incentive Compensation hereunder, provided that such recoupment is undertaken reasonably promptly. The Administrator may, in its discretion, seek recoupment from a Covered Officer from any of the following sources or a combination thereof, whether the applicable compensation was approved, awarded, granted, payable or paid to the Covered Officer prior to, on or after the Effective Date: (i) direct repayment of Recoverable Incentive Compensation previously paid to the Covered Officer; (ii) cancelling prior cash or equity-based awards (whether vested or unvested and whether paid or unpaid); (iii) cancelling or offsetting against any planned future cash or equity-based awards; (iv) forfeiture of deferred compensation, subject to compliance with Code Section 409A; and (v) any other method authorized by applicable law or contract. Subject to compliance with any applicable law, the Administrator may effectuate recoupment under this Policy from any amount otherwise payable to the Covered Officer, including amounts payable to such individual under any otherwise applicable Company plan or program, *e.g.*, base salary, bonuses or commissions and compensation previously deferred by the Covered Officer. The Administrator need not utilize the same method of recovery for all Covered Officers or with respect to all types of Recoverable Incentive Compensation.

(e) No Indemnification of Covered Officers. Notwithstanding any indemnification agreement, applicable insurance policy or any other agreement or provision of the Company's certificate of incorporation or bylaws to the contrary, no Covered Officer shall be entitled to indemnification or advancement of expenses in connection with any enforcement of this Policy by the Company, including paying or reimbursing such Covered Officer for insurance premiums to cover potential obligations to the Company under this Policy.

(f) Indemnification of Administrator. Any members of the Administrator, and any other members of the Board who assist in the administration of this Policy, shall not be personally liable for any action, determination or interpretation made with respect to this Policy and shall be indemnified by the

Company to the fullest extent under applicable law and Company policy with respect to any such action, determination or interpretation. The foregoing sentence shall not limit any other rights to indemnification of the members of the Board under applicable law or Company policy.

(g) No "Good Reason" for Covered Officers. Any action by the Company to recoup or any recoupment of Recoverable Incentive Compensation under this Policy from a Covered Officer shall not be deemed (i) "good reason" for resignation or to serve as a basis for a claim of constructive termination under any benefits or compensation arrangement applicable to such Covered Officer, or (ii) to constitute a breach of a contract or other arrangement to which such Covered Officer is party.

5. ADMINISTRATION

Except as specifically set forth herein, this Policy shall be administered by the Administrator. The Administrator shall have full and final authority to make any and all determinations required under this Policy. Any determination by the Administrator with respect to this Policy shall be final, conclusive and binding on all interested parties and need not be uniform with respect to each individual covered by this Policy. In carrying out the administration of this Policy, the Administrator is authorized and directed to consult with the full Board or such other committees of the Board as may be necessary or appropriate as to matters within the scope of such other committee's responsibility and authority. Subject to applicable law, the Administrator may authorize and empower any officer or employee of the Company to take any and all actions that the Administrator, in its sole discretion, deems necessary or appropriate to carry out the purpose and intent of this Policy (other than with respect to any recovery under this Policy involving such officer or employee).

6. SEVERABILITY

If any provision of this Policy or the application of any such provision to a Covered Officer shall be adjudicated to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect any other provisions of this Policy, and the invalid, illegal or unenforceable provisions shall be deemed amended to the minimum extent necessary to render any such provision or application enforceable.

7. NO IMPAIRMENT OF OTHER REMEDIES

Nothing contained in this Policy, and no recoupment or recovery as contemplated herein, shall limit any claims, damages or other legal remedies the Company or any of its affiliates may have against a Covered Officer arising out of or resulting from any actions or omissions by the Covered Officer. This Policy does not preclude the Company from taking any other action to enforce a Covered Officer's obligations to the Company, including, without limitation, termination of employment and/or institution of civil proceedings. This Policy is in addition to the requirements of Section 304 of the Sarbanes-Oxley Act of 2002 ("**SOX 304**") that are applicable to the Company's Chief Executive Officer and Chief Financial Officer and to any other compensation recoupment policy and/or similar provisions in any employment, equity plan, equity award, or other individual agreement, to which the Company is a party or which the Company has adopted or may adopt and maintain from time to time; provided, however, that compensation recouped pursuant to this Policy shall not be duplicative of compensation recouped pursuant to SOX 304 or any such compensation recoupment policy and/or similar provisions in any such employment, equity plan, equity award, or other individual agreement except as may be required by law.

8. AMENDMENT; TERMINATION

The Administrator may amend, terminate or replace this Policy or any portion of this Policy at any time and from time to time in its sole discretion. The Administrator shall amend this Policy as it deems necessary to comply with applicable law or any Listing Standard.

9. SUCCESSORS

This Policy shall be binding and enforceable against all Covered Officers and, to the extent required by Rule 10D-1 and/or the applicable Listing Standards, their beneficiaries, heirs, executors, administrators or other legal representatives.

10. REQUIRED FILINGS

The Company shall make any disclosures and filings with respect to this Policy that are required by law, including as required by the SEC.

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