UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2022

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 001-40192

Longboard Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**84-5009619**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
4275 Executive Square, Suite 950 La Jolla, CA	**92037**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (619) 592-9775

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	LBPH	The Nasdaq Global Market

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 ☐ NO ☒

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 ☐ NO ☒

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 ☒ NO ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted 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 such files). YES ☒ NO ☐

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

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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. ☐

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. ☐

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). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). YES ☐ NO ☒

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant, based on the closing price of the shares of common stock on The Nasdaq Stock Market on June 30, 2022, was approximately $52,100,000.

As of February 28, 2023, the registrant had 22,965,350 shares of common stock, $0.0001 par value per share, outstanding, comprised of 19,335,950 shares of voting common stock, $0.0001 par value per share and 3,629,400 shares of non-voting common stock, $0.0001 par value per share.

DOCUMENTS INCORPORATED BY REFERENCE

Certain information required by Part III of this Annual Report on Form 10-K is incorporated by reference from the registrant's Definitive Proxy Statement for the Annual Meeting of Stockholders to be held in May 2023, which will be filed with the Securities and Exchange Commission on or before May 2, 2023.

Auditor Firm Id:	185	Auditor Name:	KPMG LLP	Auditor Location:	San Diego, CA

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K (this Annual Report) contains forward-looking statements that involve risks and uncertainties. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. All statements other than statements of historical facts contained in this Annual Report are forward-looking statements, which speak only as of the date they are made and are not guarantees of future performance. In some cases, you can identify forward-looking statements by words such as "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "seek," "should," "target," "will," "would," or the negative or plural of these words or other comparable terminology. These forward-looking statements generally relate to future events or our future financial or operating results and may include, but are not limited to, statements about:

- our plans to research, develop and commercialize our product candidates;
- the initiation, progress, success, cost and timing of our clinical trials and product development activities;
- the therapeutic potential of our product candidates, and the disease indications for which we intend to develop our product candidates;
- our ability and timing to advance our product candidates into, and to successfully initiate, conduct, enroll and complete, clinical trials;
- our ability to manufacture our product candidates for clinical development and, if approved, for commercialization, and the timing and costs of such manufacture;
- the performance of third parties in connection with the development and manufacture of our product candidates, including third parties conducting our clinical trials as well as third-party suppliers and manufacturers;
- our ability to obtain funding for our operations, including funding necessary to initiate and complete clinical trials of our product candidates;
- the size and growth of the potential markets for our product candidates and our ability to serve those markets;
- the potential scope, duration and value of our intellectual property rights;
- our ability, and the ability of our licensors, to obtain, maintain, defend and enforce intellectual property rights protecting our product candidates, and our ability to develop and commercialize our product candidates without infringing the proprietary rights of third parties;
- our ability to recruit and retain key personnel;
- the effects on our operations of general political and economic conditions, including the COVID-19 pandemic, the invasion of Ukraine by Russia, economic slowdowns, recessions or market corrections, inflation, rising interest rates and tightening of credit markets resulting from the pandemic, the conflict in Ukraine or another cause; and
- other risks and uncertainties, including those described under Part II, Item 1A, "Risk Factors" of this Annual Report.

Any forward-looking statements in this Annual Report reflect our current views with respect to future events or to our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under Part I, Item 1A, "Risk Factors" of this Annual Report. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

Unless the context otherwise indicates, references in this Annual Report to the terms "Longboard", the "Company", "we", "our", and "us" refer to Longboard Pharmaceuticals, Inc. and references to our "common stock" refers to our voting common stock.

SUMMARY OF RISKS ASSOCIATED WITH OUR BUSINESS

An investment in shares of our common stock involves a high degree of risk. Below is a list of the more significant risks associated with our business. This summary does not address all of the risks that we face. Additional discussion of the risks listed in this summary, as well as other risks that we face, are set forth under Part I, Item 1A, "Risk Factors" in this Annual Report. Some of the material risks associated with our business include the following:

- We have a limited operating history, and we have incurred losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future. We may never generate any revenue or become profitable or, if we achieve profitability, we may not be able to sustain it.
- We will need substantial additional capital to finance our operations, which may not be available on acceptable terms, or at all. The effects of macroeconomic conditions and geopolitical events, including economic slowdowns, recessions, inflation, rising interest rates and tightening of credit markets caused by COVID-19 or another pandemic, the conflict in Ukraine or otherwise, may limit our access to capital. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate certain of our product development efforts or other operations.
- We are early in our development efforts and have only one product candidate, LP352, in early clinical development. All of our other product candidates are in the preclinical or research stage. If we are unable to advance our product candidates in clinical development, obtain regulatory approval and ultimately commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed.
- Clinical and preclinical drug development involves a lengthy and expensive process with an uncertain outcome. The results of prior clinical trials and early preclinical studies and clinical trials of our product candidates are not necessarily predictive of future results.
- Because we have multiple product candidates in our pipeline and are considering a variety of target indications, we may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.
- The regulatory approval processes of the U.S. Food and Drug Administration (FDA) and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.
- If the market opportunities for our product candidates are smaller than we estimate, even assuming approval of a product candidate, our business may suffer. Because the patient populations in the market for our product candidates may be small, we must be able to successfully identify patients and acquire a significant market share to achieve profitability and growth.
- We currently have no marketing and sales organization and have no experience as a company in commercializing products, and we may have to invest significant resources to develop these capabilities. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our products, we may not be able to generate product revenue.
- COVID-19 has impacted and could continue to adversely impact our business.
- We intend to rely on third parties to conduct, supervise and monitor our preclinical studies and clinical trials, and if those third parties perform in an unsatisfactory manner, it may harm our business.
- Our principal stockholders and management own a significant percentage of our stock and are able to exert significant control over matters subject to stockholder approval. Our stock market price may be negatively affected if our principal stockholders and management sell some or all of their stock.
- We depend on intellectual property licensed from third parties, including Arena Pharmaceuticals, Inc. (Arena), and the failure by us or our licensors to protect the licensed intellectual property or the termination of our license could result in the loss of significant rights, which would harm our business.
- If we are unable to obtain and maintain patent protection for our current or any future product candidates, or if the scope of the patent protection obtained is not sufficiently broad, we may not be able to compete effectively in our markets.

PART I

Item 1. Business.

Overview

We are a clinical-stage biopharmaceutical company focused on developing novel, transformative medicines for neurological diseases. We were formed in January 2020 by Arena Pharmaceuticals, Inc. (Arena) to advance a portfolio of centrally acting product candidates designed to be highly selective for specific G protein-coupled receptors (GPCRs). Our small molecule product candidates were discovered out of the same platform at Arena that represents a culmination of more than 20 years of world-class GPCR research. Arena was purchased by Pfizer, Inc. (Pfizer) on March 11, 2022 and is now a wholly-owned subsidiary of Pfizer.

We are currently focused on developing the following product candidates in our pipeline:

- LP352, an oral, centrally acting, 5-hydroxytryptamine 2C receptor subtype (5-HT2C) superagonist, currently in a Phase 1b/2a clinical trial (the PACIFIC Study) expected to evaluate 50 participants ages 12 to 65 years old with developmental and epileptic encephalopathies (DEEs), which may include Dravet syndrome, Lennox-Gastaut syndrome (LGS), tuberous sclerosis complex (TSC), CDKL5 deficiency disorder (CDD), SCN2A-related disorders, among others, with study enrollment expected to be completed in the first half of 2023 and topline data expected in the second half of 2023; and
- LP659, a centrally acting, sphingosine-1-phosphate (S1P) receptor subtypes 1 and 5 (S1P1,5) modulator, for which we anticipate initiating a Phase 1 clinical study in healthy volunteers in the first half of 2023 and anticipate topline single ascending dose (SAD) data in the second half of 2023.

LP352, our most advanced product candidate, is a potential best-in-class serotonin receptor agonist anti-seizure medication (ASM) for DEEs. LP352 has shown no measurable impact on 5-HT2B and 5-HT2A receptor subtypes in preclinical studies to date. 5-HT2B and 5-HT2A receptor agonism have been associated with significant adverse side effects, including valvular heart disease and pulmonary arterial hypertension in the case of the 5-HT2B receptor, and euphoria, hallucination, and dissociation in the case of the 5-HT2A receptor. LP352 has the potential to be a clinically differentiated 5-HT2C superagonist for patients with DEEs, a group of severe early-childhood onset epilepsies characterized by refractory seizures and developmental delay and/or regression. Certain compounds in the 5-HT2C agonist class, including FINTEPLA and lorcaserin, have been shown to produce clinical benefit in epilepsy patients, although the side effect profiles of available non-selective 5-HT2 therapies may limit their use due to their activity on receptor subtypes 5-HT2B and/or 5-HT2A. We believe LP352's potential for high selectivity and novel chemistry may reduce seizures and lead to differentiated non-seizure outcomes in DEE patients, as well as overcome the known or perceived safety limitations of available drugs in the 5-HT2 class.

We are also developing LP659, a centrally acting, S1P1,5 receptor modulator for which aberrant modulation has been shown to be involved in a wide range of neurological diseases. Based on its novel chemistry, potential for high selectivity for specific subtypes of GPCRs and favorable blood-brain-barrier penetration, we believe LP659 has the potential to address multiple inflammatory neurological conditions. LP659 was designed by Arena to have more optimized pharmacology and pharmacokinetics (PK) for its intended S1P receptor subtypes, compared to other known compounds. We believe this potential selectivity and specificity could result in a superior profile in the clinic compared to drugs that may not fully engage the intended GPCR target, may cause off-target activity, or may be associated with other undesirable effects.

Our Pipeline

Our product candidates are targeted towards specific GPCRs. GPCRs mediate cell-to-cell communication in humans, and approximately 40% of prescription drugs currently on the market target mainly GPCRs, making GPCRs a highly validated class of drug targets. Our GPCR product candidates are designed to increase the likelihood of the desired pharmacology and PK and minimize the risk of off-target effects.

The following table provides an overview of our product candidates currently in development:

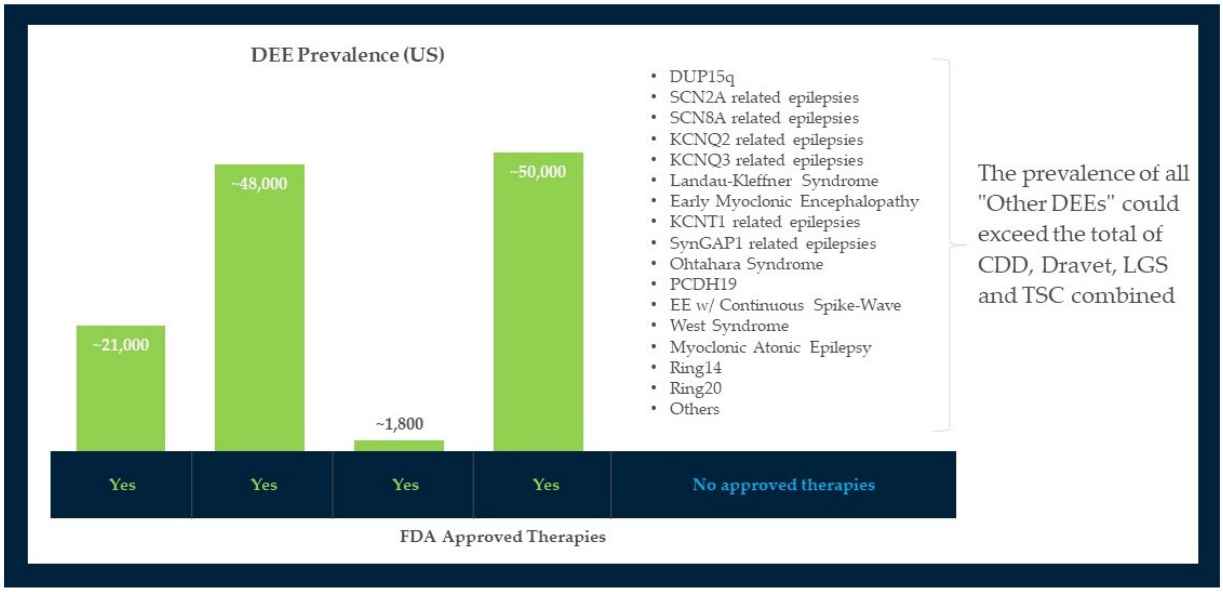
Program	MOA	Therapeutic Area	Preclinical	Ph I	Ph II	Ph III	Anticipated 2023 Milestones
LP352	5-HT2C Superagonist	DEEs and other refractory epilepsies					• Ph 1b/2a PACIFIC Study Enrollment Completion – H1 2023 • PACIFIC Study Topline Data – H2 2023
LP659	S1P Receptor Modulator	Multiple neurological diseases					• Phase 1 Initiation – H1 2023 • Phase 1 SAD Topline Data – H2 2023

- *We hold exclusive rights to other product candidates, including LP143 and nelotanserin, through the Arena License Agreement*
- *We are eligible to receive royalties of 9.5% - 18.5% on sales of lorcaserin if approved for commercialization through the Arena Royalty Purchase Agreement*

LP352

We are developing LP352, an oral, centrally acting, 5-HT2C superagonist for DEEs and other epileptic disorders. LP352 is the only 5-HT2C receptor agonist being dose optimized specifically for DEEs, a group of severe early-childhood onset epilepsies characterized by refractory seizures and developmental delay and/or regression. These diseases are often progressive and resistant to treatment. DEEs encompass a diverse range of over 25 syndromes, of which only four currently have FDA-approved therapies. We believe that LP352 could be a treatment for individuals with DEEs where no options are available and a potentially safer, more efficacious, easy to add-on treatment option for individuals with syndromes where current therapies are inadequate.

The following diagram illustrates the current DEE landscape:



LP352 selectively targets the 5-HT2C receptor, which has been shown to upregulate the release of gamma-aminobutyric acid (GABA), a principal neurotransmitter in the brain. This release of GABA increases the threshold for neuronal hyperexcitability, and decreases the likelihood of seizure occurrences. We believe LP352 has the mechanistic potential to reduce seizures in a broad number of DEEs.

We initiated our first clinical trial in patients with DEEs (the PACIFIC Study) in the first quarter of 2022. We plan to evaluate 50 patients, ages 12 to 65 years old, with a range of DEEs, across sites in the United States and Australia. Topline data is expected in the second half of 2023. In addition, we have conducted multiple Phase 1 clinical trials in healthy volunteers with LP352, and will continue to conduct such trials to further explore the potential of LP352.

LP659

We are developing LP659, a centrally acting, S1P1,5 receptor modulator for inflammatory neurological conditions. LP659 was designed for optimized pharmacology, PK and engagement of S1P1,5, which may lead to improved efficacy and safety. LP659 was designed to avoid the negative effects connected to the receptor subtypes 2 and 3, which may be associated with more serious, off-target cardiac, pulmonary, and cancer-related effects. Aberrant S1P receptor modulation has been shown to be involved in a wide range of neurological diseases, including multiple sclerosis, lupus, Parkinson's disease and Alzheimer's disease. Preclinical data demonstrated an initial dose-dependent decrease in disease progression over 17 days in a mouse model of demyelinating disease. LP659 rapidly reduced circulating lymphocytes, which returned to baseline after its clearance. We believe LP659 has high oral bioavailability with a direct impact on CNS glial cell S1P receptors. We anticipate initiating a Phase 1 clinical trial in healthy volunteers for LP659 in the first half of 2023. Topline SAD data is expected in the second half of 2023.

Our Company History and Team

We were established in January 2020 as Arena Neuroscience, Inc., a wholly owned subsidiary of Arena, based in San Diego, California. We changed our name to Longboard Pharmaceuticals, Inc. and launched as an independent company in October 2020. Building on Arena's 20-year history in discovering, developing and optimizing GPCR therapies, we believe we are well positioned to execute our clinical development programs. Our current product candidates LP352 and LP659 were designed by Arena to have distinct chemistry and therapeutic profiles from Arena's other product candidates with similar mechanisms of actions. Namely, LP352 was designed to be centrally acting and a more specific and selective 5-HT2C subtype receptor agonist than lorcaserin, and LP659 was designed to be a centrally acting S1P1,5 receptor modulator with differentiated selectivity and blood brain penetration compared to etrasimod (an S1P1 receptor modulator that is Arena's lead product candidate and the subject of an New Drug Application (NDA) submission accepted for review in December of 2022 following Arena's acquisition by Pfizer Inc. (Pfizer)).

In October 2020, we entered into a License Agreement (Arena License Agreement) with Arena, pursuant to which Arena granted us an exclusive, royalty bearing, sublicensable, worldwide license to develop and commercialize LP352, LP659, LP143 and certain 5-HT2A compounds (pharmaceutical products containing any such product candidates, the Licensed Products). In January 2022, we amended the Arena License Agreement to add an additional program, and in September 2022 we further amended the Arena License Agreement to expand the field of the license of LP659 and provide Arena a right of first negotiation to acquire certain development and commercial rights to LP659 products.

Our Strategy

Our goal is to develop therapies targeting well-characterized receptor pathways with optimized pharmacology and PK properties to transform the lives of patients with neurological diseases, initially focused on rare neurological diseases. Key elements of our strategy to achieve this goal include:

- Advance our lead program LP352 through clinical development and approval in DEEs. There are only treatment options for four out of the over 25 DEEs, currently. Additionally, existing treatment options for these rare neurological diseases have significant limitations, and, if approved, we believe LP352 would represent a potential therapeutic advancement for patients.

- Continue preclinical development of LP659, an S1P1,5 receptor modulator, across a range of neurological diseases and progress into clinical development. We expect to initiate a Phase 1 clinical study in healthy volunteers in the first half of 2023 and anticipate topline SAD data in the second half of 2023.

- Identify additional product candidates, including those that we currently hold rights to, and expand current candidates into additional neurological diseases. We see potential for our current product candidates to be evaluated in clinical trials outside of their initial indications and will evaluate additional indications to maximize the potential of our pipeline. We also plan to continue to identify and develop additional novel product candidates that align with our strategy.

- Explore strategic collaborations to maximize the value of our product candidates. We plan to explore collaborations opportunistically to maximize the value of our pipeline. We intend to retain significant economic and commercial rights to our programs in key geographic areas that are core to our long-term strategy.

Our Product Candidates

LP352, an oral, centrally acting, 5-HT2C superagonist

We are developing LP352, an oral, centrally acting, 5-HT2C superagonist for DEEs and other epileptic disorders. LP352 is designed to selectively target 5-HT2C, which has been shown to upregulate the release of GABA, a principal inhibitory neurotransmitter in the brain. The release of GABA increases the threshold for neuronal hyperexcitability and decreases the likelihood of seizure occurrence. We believe LP352 has the mechanistic potential to reduce the frequency of seizures in Dravet syndrome and LGS as well as a broader epilepsy population. We have conducted multiple clinical trials in healthy volunteers with LP352. We initiated the PACIFIC Study in patients with DEEs in the first quarter of 2022 and expect to have topline data in the second half of 2023.

Background on Epilepsy

Epilepsy covers a broad range of disorders and is characterized by spontaneous and recurrent seizures, or bursts of neuronal hyperactivity. Seizures are caused by a disrupted balance between excitatory and inhibitory signaling at the synaptic level. Excitatory synaptic activity is normally regulated by inhibitory interneurons, but disruptions to this regulatory process can result in hyperexcitability. Common aberrations include mutations to ion channels or neurotransmitter genes or proteins that regulate signaling, such as GABA, and disruptions lead to the signaling aberrations characteristic of epileptic disorders. For example, Dravet syndrome is characterized by mutations in the sodium ion channel, the ion channel critical for the generation and propagation of action potentials in neurons, and which ordinarily plays a crucial role in inhibitory signaling.

Overview of the Forms of Epilepsy

Epilepsy spans all age groups and in many cases is debilitating, with a large portion of patients resistant to pharmacologic treatment, underscoring a large unmet need. Epilepsy is currently estimated to affect up to 1.2% percent of the U.S. population or approximately 3.4 million individuals, with roughly 150,000 new cases diagnosed each year. We are initially focused on DEEs, which are a group of severe early childhood-onset epilepsies characterized by refractory seizures and developmental delay and/or regression and include Dravet syndrome and LGS, among others, but the 5-HT2C pathway has been implicated in a broader set of epilepsies.

Dravet Syndrome - Dravet syndrome is an early childhood-onset CNS disease that results in severe epileptic seizures typically occurring within the first year after birth. Incidence for Dravet syndrome is approximately 1:15,000 in the United States, and 90% of the associated mutations are de novo (not passed from a parent). Mortality rate for Dravet syndrome patients is higher than general epilepsy patients, with a rate of 15-20% by adulthood. The disease is genetically linked, with 70% to 85% of cases characterized by mutations in the SCN1A gene. Mutations cause defects in the function of the sodium ion channel. Seizures due to Dravet syndrome are typically difficult to control and require life-long treatment.

Lennox Gastaut Syndrome - LGS is a severe form of childhood-onset epilepsy with prevalence of approximately 1:7,000 in the United States. The age of onset is typically between three and five years and affected children typically experience cognitive dysfunction, leading to developmental and behavioral problems. LGS is characterized by multiple seizure types, with the most common associated seizures being tonic and atonic seizures. Seizures due to LGS are difficult to control and generally require life-long treatment. The pathophysiology of LGS is less known than Dravet syndrome.

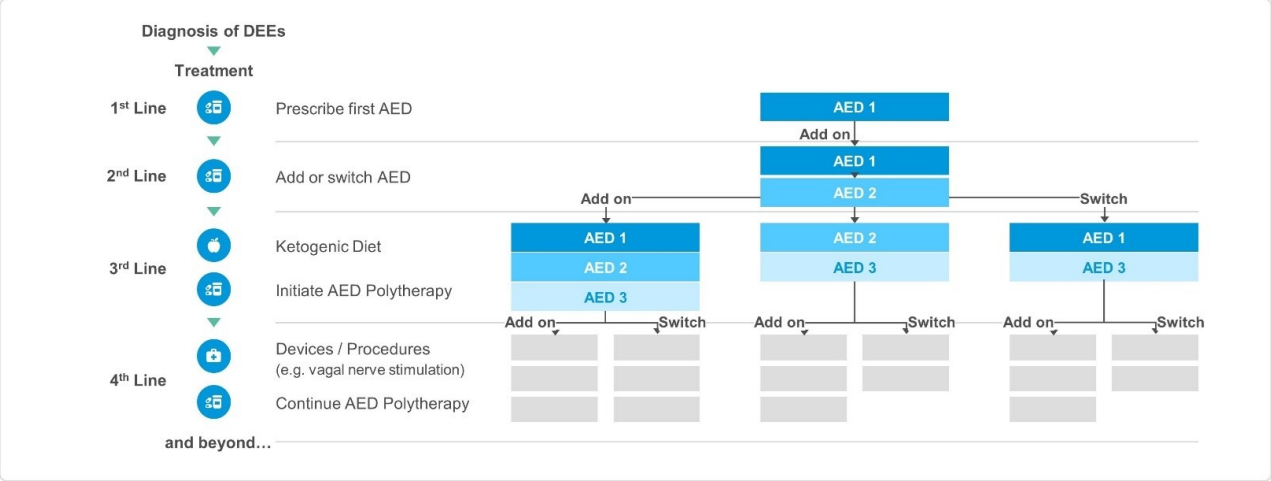
Tuberous Sclerosis Complex (TSC) - TSC is a genetic disorder that causes tumors to form in many different organs, primarily in the brain, eyes, heart, kidney, skin and lungs. The aspects of TSC that most strongly impact quality of life are generally associated with the brain: seizures, developmental delay, intellectual disability and autism. Current estimates place TSC-affected births at 1:6,000 in the United States. Nearly 1 million people worldwide are estimated to have TSC, with approximately 50,000 in the United States.

CDKL5 Deficiency Disorder (CDD) – CDD is a rare developmental epileptic encephalopathy caused by mutations in the CDKL5 gene, and this can manifest in a broad range of clinical symptoms and severity. The hallmarks are early-onset, intractable epilepsy and neurodevelopmental delay impacting cognitive, motor, speech, and visual function. Although rare, the occurrence is believed to be approximately 1:40,000 -60,000 live births in the United States, making it one of the most common forms of genetic epilepsy.

Current Treatment Paradigm

DEEs are commonly treated with multiple combinations of anti-epileptic drugs (AEDs) though physician preference for administered therapies differs across different epilepsy types. Currently available AEDs have limited long-term efficacy with many patients cycling through multiple lines of treatment to try to optimize efficacy. Non-pharmaceutical therapies for epilepsy patients include a ketogenic diet, vagus nerve stimulation (VNS), and surgery for some patients.

The following table is illustrative of the typical treatment paradigm for DEEs:



Dravet syndrome and LGS are two types of epilepsies that are difficult to treat given that most patients are refractory to antiseizure medications. The seizures for a vast majority of these patients remain uncontrolled and patients typically require multiple lines of treatment. FDA approved drugs in Dravet syndrome include Epidiolex® (cannabidol), FINTEPLA® (fenfluramine) and DIACOMIT® (stiripentol). Epidiolex is also approved in LGS and TSC. Ztalmy is approved for CDD. Despite these treatments being available, we believe a significant unmet medical need remains.

Background on GABA and Neurotransmission

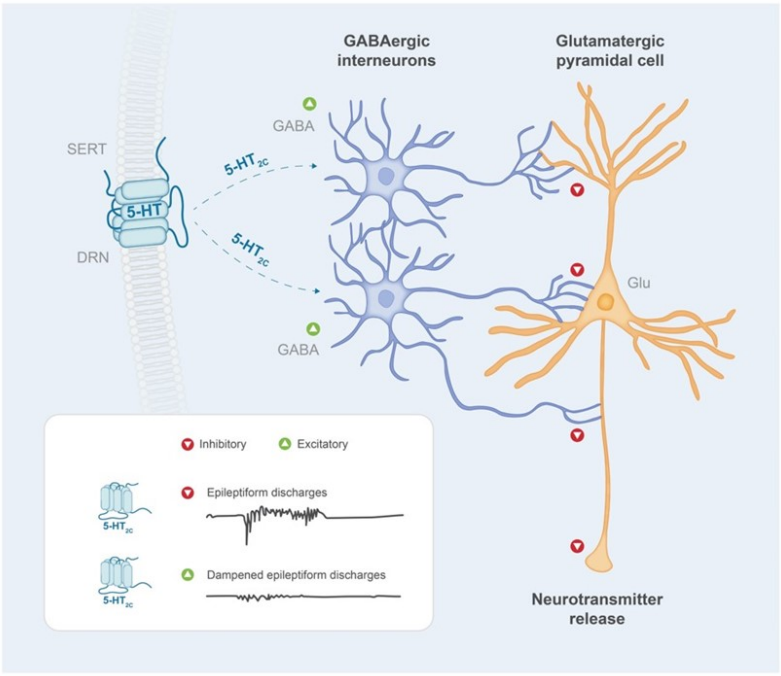
GABA is a principal neurotransmitter in the brain and binds to receptors inside and outside the synaptic gap. GABA plays key roles in neuronal inhibition, and reduction of GABA levels has been shown to result in a decline of this inhibition. Lack of GABA-mediated inhibition subsequently leads to the chronic activation of post-synaptic neurons characteristic of seizures.

5-HT2 Receptors

5-HT receptors, or serotonin receptors, are widely expressed in neural networks. Serotonin plays a key role in modulating neurotransmission, as agents elevating extracellular serotonin levels have been shown to inhibit focal and generalized seizures while agents reducing serotonin levels have been shown to lower the threshold for seizures. To date, 14 receptor subtypes of 5-HT receptors have been characterized and are grouped into seven classes. The two main classes are 5-HT1 and 5-HT2. 5-HT2 receptors are G-coupled membrane proteins that are distinguished by their function of increasing intracellular calcium levels (Ca2+) and activation of protein kinase C. Three subtypes exist: 5-HT2A, 5-HT2B and 5-HT2C, with the 5-HT2A and 5-HT2C receptor subtypes primarily expressed in the CNS and 5-HT2B primarily expressed in the peripheral nervous system. All subtypes have been shown to modulate neurotransmission, though the 5-HT2B receptor has been implicated with valvular heart disease and pulmonary arterial hypertension and the 5-HT2A receptor subtype has been implicated with hallucinations and mild to severe anxiety.

5-HT2C is one of the many binding sites for serotonin and is expressed on GABAergic, glutamatergic, and dopaminergic neurons. Multiple preclinical studies have suggested that 5-HT2C plays an important role in the inhibition of seizures. For example, in a knockout mouse model, mice missing the 5-HT2C receptor subtype were shown to have a lower threshold for seizures and experienced spontaneous convulsions. Preclinical models suggest that activation of 5-HT2C regulates GABA and glutamate pathophysiology seen in seizure disorders. Excitatory glutamate release is directly and indirectly regulated by 5-HT actions on GABA interneurons and pyramidal neurons. Research proposes that neuronal hyperexcitability occurs during the transition to seizure when excitatory glutamatergic activity increases while inhibitory GABAergic synaptic input is weakened. It is thought that 5-HT2C agonists, acting on GABA interneurons, inhibit excitatory glutamatergic activity, thereby decreasing neuronal action potential firing and downstream electrical activity.

This downstream electrical activity is illustrated in the below:



The 5-HT2 class and 5-HT2C subtype have additionally been shown in the clinic to reduce seizure frequencies.

FINTEPLA (fenfluramine) - FINTEPLA, a 5-HT2 receptor agonist with activity on 5-HT2A, 5-HT2B and 5-HT2C receptors, was initially developed as monotherapy treatment for adult obesity as well as in combination with phentermine (fen-phen). Later, however, reports were published documenting cases of valvular heart disease and pulmonary arterial hypertension, causing the drug to be pulled from the market in 1997. More recently, Zogenix, Inc. (Zogenix) began developing fenfluramine for Dravet syndrome, LGS, and other rare epilepsies using lower doses of fenfluramine. In June 2020, the FDA approved fenfluramine for the treatment of seizures associated with Dravet syndrome. Approval was based on data from two randomized, double-blinded, placebo-controlled Phase 3 clinical trials, as well as safety data from an open-label extension trial in which patients received FINTEPLA for up to three years. Patients administered the therapy demonstrated significant reductions in monthly convulsive seizure frequency compared to placebo. However, the FDA placed a boxed warning in FINTEPLA's label noting an association between serotonergic drugs with 5-HT2B agonist activity, including fenfluramine, and valvular heart disease and pulmonary arterial hypertension. FINTEPLA is available only through a restricted distribution program called the FINTEPLA REMS program, in which prescribers and patients must be enrolled. Cardiac monitoring via echocardiogram is required pretreatment, during treatment and after treatment with FINTEPLA. In June 2022, the FDA approved fenfluramine for the treatment of seizures associated with LGS. Zogenix was acquired by UCB in June 2022 for approximately $1.9 billion.

Lorcaserin - Lorcaserin, a 5-HT2C agonist, was discovered by Arena, approved by the FDA for weight management, and marketed as BELVIQ by Eisai Inc. Lorcaserin was withdrawn from the market at the request of the FDA following the FDA's analysis of the CAMELLIA-TIMI 61 clinical trial, for which patients in the lorcaserin group demonstrated a numerically higher but not a statistically significantly higher rate of total cancer diagnoses (7.7% vs 7.1% placebo). Based on the results of this clinical trial, the FDA concluded that the risks of lorcaserin outweigh the benefits, and requested that lorcaserin be withdrawn from the market for the approved indication of weight management in February 2020. The FDA authorized an expanded access program for patients with Dravet syndrome to continue to receive lorcaserin.

Lorcaserin has demonstrated the potential to reduce seizures in patients with Dravet syndrome and refractory epilepsies. A National Institutes of Health funded study conducted at the University of California, San Francisco showed that several 5-HT receptor modulating compounds, including lorcaserin, reduced seizure-like activity in a zebrafish model of Dravet syndrome.

Lorcaserin has been tested in a small study of "off-label" use in five children who each had an SCN1A (sodium channel) gene mutation or a clinical diagnosis of Dravet syndrome, and failed at least two medications. Lorcaserin was initially dosed at 2.5 mg at bedtime and gradually increased weekly as needed to a maximum dose of 10 mg twice a day or 0.3 mg/kg/day, whichever occurred

first. One patient was initially seizure-free for three weeks, one patient was seizure-free for two weeks, and a third patient had one to two seizure-free days per week. All five patients exhibited a reduction in the total number of seizures after three months on treatment.

A follow-up retrospective study conducted in 35 lorcaserin-treated refractory epilepsy patients found a 50% reduction in mean monthly frequency of seizures in LGS patients (n = 9), a 43% reduction in patients with Dravet syndrome (n = 20), and a 23% reduction in patients with other epilepsies (n = 6). Overall, the study demonstrated a 47.7% median percentage reduction in mean monthly frequency of motor seizures from baseline.

In September 2020, following consultation with the FDA, Eisai Inc. initiated a Phase 3 clinical trial of lorcaserin in patients with Dravet syndrome.

Our Solution

LP352 in Epilepsies

LP352 is an oral, centrally acting, 5-HT2C superagonist. A superagonist displays higher receptor signaling output than the natural agonist. As a 5-HT2C superagonist, LP352 is designed to modulate GABA inhibition and as a result, suppress the hyperexcitability that is characteristic of seizures. Based on its potential mechanism of action, we believe that LP352 has the potential to reduce the frequency of seizures in Dravet syndrome, LGS, and across a broad range of refractory epilepsies. 5-HT2C agonism has shown clinical benefit in epilepsy patients, however, currently available 5-HT2 agonists have been associated with significant adverse events (AEs). LP352 was discovered at Arena, and was developed to be the next-generation to lorcaserin. LP352 has novel chemistry and attributes, and was designed with the goal of being a safer, more effective 5-HT2C superagonist. We hold worldwide rights to LP352 through the Arena License Agreement.

LP352 has demonstrated selectivity on the 5-HT2C receptor subtype with no detected activity on the 5-HT2B and 5-HT2A receptor subtypes in in vitro preclinical studies, as shown in the following table:

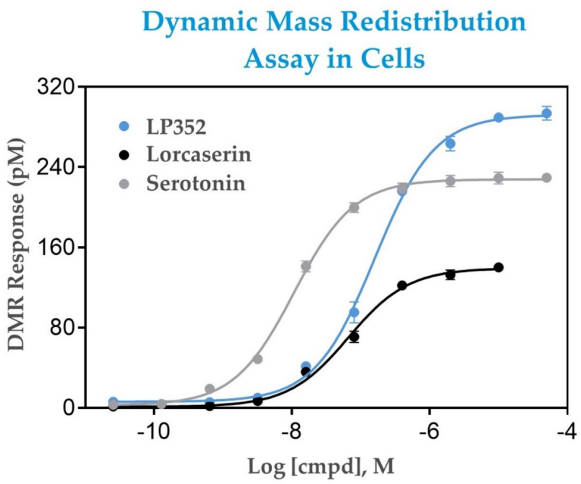
	Serotonin Receptor Subtype	EC_{50}, nM	Ki, nM	Selectivity 5-HT2C vs 5-HT2B	Selectivity 5-HT2C vs 5-HT2A	Potential Adverse Events Per Receptor Subtype
LP352 5-HT2C Superagonist	**5-HT2C**	**~120**	**~50**	**>200x**	**>200x**	CNS, GI
	5-HT2B	Not detectable	Not detectable			n/a
	5-HT2A	Not detectable	Not detectable			n/a
Nordexfenfluramine (an active metabolite of fenfluramine)[1]	5-HT2C	72.4	10.4	0.94x	11.5x	CNS, GI
	5-HT2B	25.7	9.8			Cardiac, Pulmonary
	5-HT2A	1778	120.2			Psychiatric
Lorcaserin[2]	5-HT2C	39	13	11.3x	7.1x	CNS, GI
	5-HT2B	2380	147			n/a
	5-HT2A	553	92			Psychiatric

1 Third party study previously commissioned by Arena
2 BELVIQ FDA approved prescribing information 06/2012
Note: The above table is for illustrative purposes only and is not a head-to-head comparison. Differences exist between in vitro study designs and methodologies, and caution should be exercised when comparing data across studies
Definitions: CNS= Central nervous system ; GI = Gastrointestinal; ASM = anti-seizure medication

The above table is for illustrative purposes only and is not a head-to-head comparison. These data were generated from different studies, and caution should be exercised when comparing data across studies. However, each of these studies followed the same basic protocol using HEK293 cells expressing recombinant human 5-HT2 receptors, and receptor densities in all of the functional assays were determined by [^{125}I]-2,5-Dimethoxy-4-iodoamphetamine, or DOI, radioligand binding.

A superagonist is a compound that is capable of producing a higher receptor response than the endogenous agonist. We have shown LP352 to be a superagonist in a dynamic mass redistribution assay measuring a holistic integrated cellular response to

lorcaserin, serotonin and LP352. This assay demonstrated that, as the concentration of LP352 increases, the cellular response is greater than the endogenous ligand serotonin and considerably more than lorcaserin. The results of this assay are demonstrated below.



LP352 added to cells and the resulting holistic integrated cellular response

LP352 Clinical Development Overview

Phase 1 Clinical Trial SAD-MAD

LP352 was evaluated in a multi-part Phase 1 clinical trial in healthy volunteers. This was a randomized, double-blind, placebo-controlled, parallel-group trial that included a SAD portion (with and without food effect) and a MAD portion (with and without dose titration). Safety and tolerability were evaluated throughout the clinical trial, and blood sampling and urine samples for PK analysis were also collected. LP352 was administered as a capsule formulation. The Phase 1 clinical trial enrolled 83 healthy participants. Doses ranging from 1 mg to 24 mg were evaluated.

SAD Results - LP352 was observed to be generally well-tolerated, and AEs were consistent with events observed with other centrally acting 5-HT2C agonists. Headache was the dose limiting AE, and mild to moderate headache was the most common treatment-emergent AE. There were no serious adverse events (SAEs) reported, and no participants dropped out due to AEs. In the SAD and food effect portions of the clinical trial, LP352 demonstrated favorable PK and pharmacodynamic effects (with target plasma exposure (minimum serum concentration) measured based on prolactin levels), including dose-dependent PK properties with proportional increases in AUC and Cmax.

MAD Results - Five doses including the maximum planned dose were evaluated. The majority of AEs were mild to moderate, with the most common being headache. AEs were generally consistent with CNS effects and expected effects of serotonergic drugs. A single SAE of anxiety was reported at the maximum planned dose two days after the last dose of study drug and subsequently resolved. LP352 demonstrated dose- and exposure-dependent increases of prolactin, suggesting proof of central 5-HT2C receptor engagement, as well as dose-dependent increases in exposure (Cmax and AUCtau). The safety and tolerability of titrating LP352 was also examined.

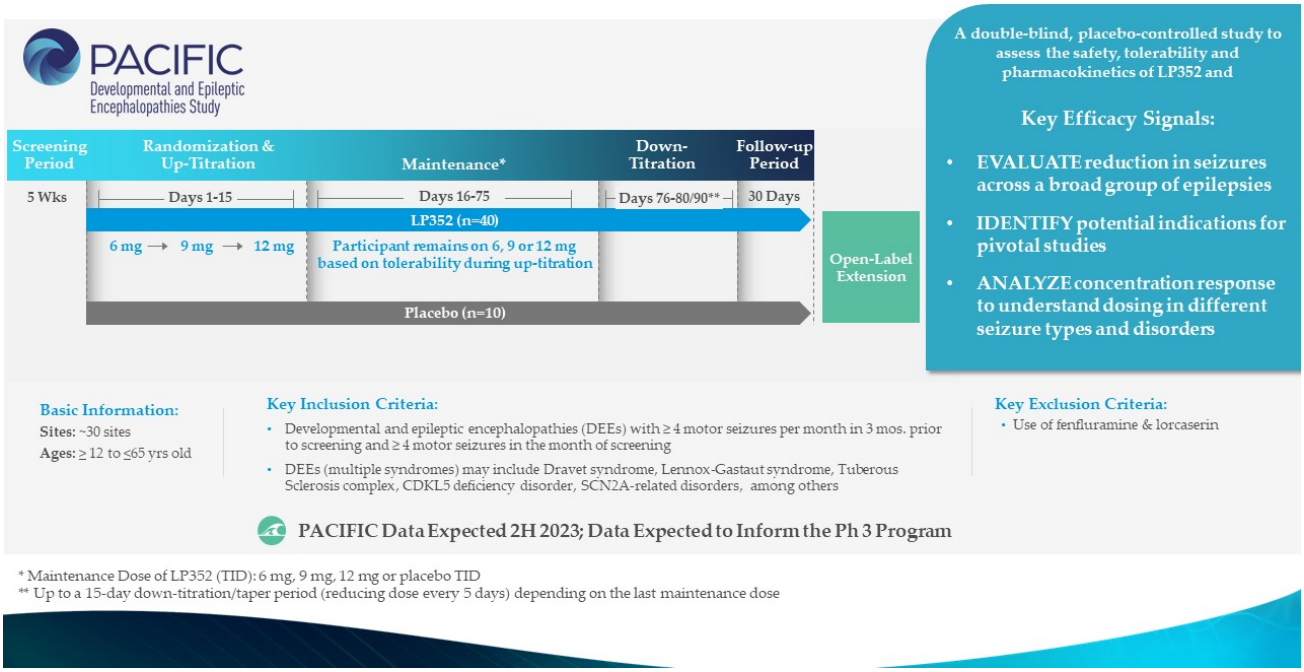
Other Phase 1 Clinical Trials

In December 2022, we announced topline data from cohorts 1 and 2 of a Phase 1 clinical trial assessing CNS PK/PD parameters in healthy adult male and female participants. In these cohorts LP352 exhibited a strong correlation between plasma and cerebrospinal fluid (CSF) PK concentration, which increased in a dose-dependent and consistent manner. In these cohorts LP352 also demonstrated early quantitative electroencephalogram (qEEG) changes and sustained effects on qEEG activity after continuous dosing in a dose-dependent manner indicating receptor engagement, and favorable safety and tolerability results were observed, with AEs generally consistent with previous clinical studies.

We are currently conducting and plan to conduct additional Phase 1 clinical trials with LP352 to further characterize and differentiate LP352.

The PACIFIC Study - a Phase 1b/2a Clinical Trial of LP352 in Patients with DEEs

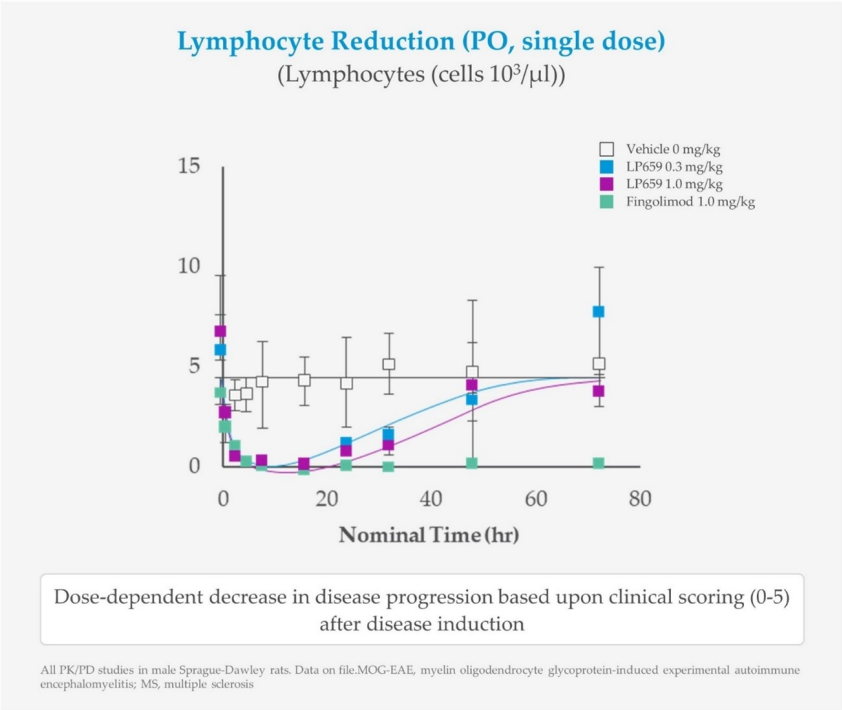
The PACIFIC Study is a Phase 1b/2a safety, tolerability and exploratory efficacy clinical trial of LP352. This is a randomized double-blind placebo-controlled trial. We plan to enroll 50 participants ages 12-65 with a variety of treatment resistant motor seizures and seizure disorders that fall into the category of DEEs. The PACIFIC Study was initiated in the first quarter of 2022, with completion of enrollment expected in the first half of 2023 and topline data expected in the second half of 2023.



LP659, a centrally acting, S1P1,5 modulator

We are developing LP659, a centrally acting, S1P1,5 receptor modulator for inflammatory neurological conditions. LP659 was designed to have optimized pharmacology, PK and engagement of S1P1,5, which may lead to improved efficacy and safety. LP659 was designed to avoid the negative effects connected to the receptor subtypes 2 and 3, which may be associated with more serious, off-target cardiac, pulmonary, and cancer-related effects. Aberrant S1P receptor modulation has been shown to be involved in a wide range of neurological diseases, including multiple sclerosis, Lupus, Parkinson's disease and Alzheimer's disease. Preclinical data in a mouse model of demyelinating disease demonstrated that LP659 treatment produced a dose-dependent decrease in disease progression over 17 days. LP659 rapidly reduced circulating lymphocytes, which returned to baseline after its clearance. In a PK/PD study to assess LP659 effects on lymphocytes in rats, male rats were given a 0.00 (vehicle control), 0.300 or 1.00 mg/kg oral dose of LP659 (n=3 per dosing group). Fingolimod, the positive control for blood lymphopenia, was given as an oral dose (n=4) at 1.00 mg/kg to a separate group of rats. Blood samples were collected at 0, 1, 3, 5, 8, 16, 24, 32, 48 and 72 hours post-dose for blood lymphocyte and

plasma drug concentration measurements. LP659 at both doses demonstrated a rapid reduction in lymphocytes which returned to baseline, whereas no return to baseline was observed for fingolimod over the study duration.

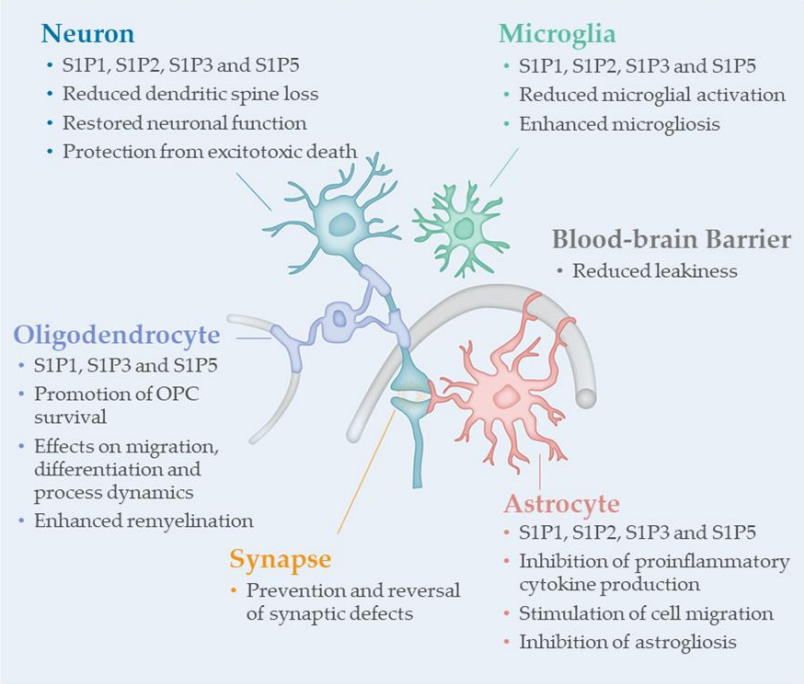


A study of CNS distribution of LP659 was conducted in rats. Male rats were dosed orally with LP659 at 1.00 mg/kg for six consecutive days. On Day 6, plasma, brain and cerebrospinal fluid samples were taken at 0, 1, 3, 5, 8, and 24 hours post-last dose (n = 3 per time point). The maximum plasma concentration of LP659 was 551 ng/mL at 3.00 hours post-dose. The maximum brain concentration of LP659 was 947 ng/mL at 8.00 hours post-dose. The mean brain to plasma ratios of LP659 at 0, 1, 3, 5, 8, and 24 hours post-last dose were 2.87, 1.25, 1.17, 1.68, 1.98, and 2.94, respectively. We believe LP659 has high oral bioavailability with a direct impact on CNS glial cell S1P receptors. We anticipate initiating a Phase 1 clinical study in healthy volunteers in the first half of 2023 and expect topline SAD data in the second half of 2023.

S1P Receptors

S1P receptors are expressed broadly in the CNS. By limiting lymphocyte circulation, S1P receptor modulators exert anti-inflammatory effects. Multiple S1P receptor modulators have been approved for the treatment of relapsing forms of multiple sclerosis. There are five known receptor types: S1P1, S1P2, S1P3, S1P4 and S1P5. S1P1, S1P2 and S1P3 receptors are expressed broadly, S1P4 is primarily expressed in immune system cells, and S1P5 is expressed primarily in the spleen and CNS. Astrocytes are the most abundant cells in the human CNS and preferentially express S1P3 and S1P1 and express S1P2 at low levels. Oligodendrocytes, oligodendrocyte precursor cells (OPC), neurons, and microglia are other brain cells that express S1P.

The various brain cell types are illustrated in the below:



Our Solution

LP659 in Neurological Diseases

LP659 acts as a S1P1 and S1P5 receptor subtypes modulator with no observed impact on S1P2 or S1P3 and has been selectively developed to cross the blood-brain barrier and target neurological diseases. In addition to its receptor subtype selectivity, LP659 has demonstrated rapid onset and offset of action (in preclinical models), with a low half-maximal inhibitory concentration in plasma (IC50 approximately 25 ng/ml in rat) to inhibit entrance of lymphocytes into blood. A single dose of LP659 causes rapid depletion of circulating lymphocytes and rapid recovery, paralleling elimination of LP659 from plasma. The S1P receptor has been well-validated in slowing the progression of neurodegeneration, notably in multiple sclerosis, for which disease area the FDA has approved four S1P receptor modulators. LP659 was designed to avoid the negative effects connected to the receptor subtypes 2 and 3, which may be associated with more serious, off-target cardiac, pulmonary, and cancer-related effects. While initial studies have shown that LP659 is efficacious in reducing the development and severity of disease in a widely accepted model of demyelinating disease (e.g., multiple sclerosis), we have not finalized a target indication as we see potential for a selective S1P1 receptor modulator to treat a spectrum of inflammatory neurological conditions.

Other Compounds

We have a license to certain compounds including LP143, a centrally acting, full cannabinoid type 2 receptor (CB2) agonist, and compounds targeting the 5-HT2A receptor, including nelotanserin. We are not currently developing any of these compounds.

License Agreement with Arena

The Arena License Agreement was originally entered into in October 2020 and amended in January 2022 and again in September 2022. Pursuant to the Arena License Agreement, Arena granted us an exclusive, royalty bearing, sublicensable, worldwide license under certain know-how and patents of Arena to LP352 for any use in humans, LP659 for the treatment of developmental, degenerative and autoimmune disease, disorders or conditions of the CNS or peripheral nervous system in humans and LP143 and certain 5-HT2A compounds for the treatment of CNS indications (excluding the treatment, prevention or amelioration of pain or any gastrointestinal, non-CNS autoimmune or cardiovascular disorder) in humans (pharmaceutical products containing any such compounds, Licensed Products). Arena further granted us a covenant not to sue under any patents or certain information of Arena with respect to each Licensed Product in its respective field. Arena retained the exclusive right to use the licensed intellectual property to

develop, make or use intermediates, pro-drugs and metabolites related to the LP352, LP659, LP143 and 5-HT2A compounds to exploit Arena's etrasimod, lorcaserin, olorinab, or temanogrel products, in any dosage strength or formulation, and we granted Arena a covenant not to sue with respect to such activities under certain of our intellectual property related to such compounds and the Licensed Products. We will assign to Arena new intellectual property developed by us related to such compounds. We have sole responsibility over development, regulatory and commercialization activities for the Licensed Products in the applicable fields, as well as commercial manufacture and supply therefor. In September 2022, we provided Arena a right of first negotiation, for a specified period of time, to acquire certain development and commercial rights to LP659 products subject to Arena and we mutually agreeing on terms. This right of first negotiation is triggered by our announcing Phase 2 clinical results relating to an LP659 product for an indication that was not in the original field of the license or if we otherwise intend to commence discussions or negotiations to license or partner rights to LP659 in such field.

As consideration for the rights granted to us under the Arena License Agreement, we will be required to pay to Arena a mid-single digit royalty on net sales of Licensed Products of LP352, and a low-single digit royalty on net sales of all other Licensed Products, by us, our affiliates or our sublicensees, subject to standard reductions. Our royalty obligations continue on a Licensed Product-by-Licensed Product and country-by-country basis until the later of the (i) tenth anniversary of the first commercial sale of such product in such country or (ii) expiration of the last-to-expire valid claim of the patents licensed to us under the Arena License Agreement covering the manufacture, use or sale of such product in such country, which we expect to run in most jurisdictions until 2036 for LP352, until 2029 for LP659 and 2030 for LP143 without taking into account patent term adjustments or extensions regimes of any country, or any additional term of exclusivity we might obtain by virtue of later filed patent applications. We also will owe Arena up to two $25.0 million commercial sales milestones if nelotanserin products (which are among the licensed 5-HT2A compounds) are developed and achieve annual net sales of $100.0 million and $500.0 million.

We may unilaterally terminate the Arena License Agreement for any reason with a specified prior notice period, and Arena may terminate the Arena License Agreement if we challenge any of the licensed patents. Either party may terminate the Arena License Agreement in the event of the other party's insolvency or for the other party's uncured material breach of the Arena License Agreement. Absent early termination, the Arena License Agreement will automatically expire upon the expiration of all our payment obligations under the Arena License Agreement.

Royalty Purchase Agreement with Arena

In October 2020, we entered into a Royalty Purchase Agreement with Arena and 356 Royalty Inc., a wholly owned subsidiary of Arena (356 Royalty), pursuant to which we purchased the right to receive all milestone payments, royalties, interest and other payments relating to net sales of lorcaserin, in all countries and territories of the world owed or otherwise payable to 356 Royalty by Eisai Inc. and Eisai Co., Ltd. (Eisai) pursuant to a Transaction Agreement dated December 28, 2016, as amended (Transaction Agreement), by and among 356 Royalty and Eisai, for an upfront payment of approximately $0.1 million. Under the Transaction Agreement, the royalty rates range from 9.5% on annual global net sales less than or equal to $175.0 million, 13.5% on annual global net sales greater than $175.0 million but less than or equal to $500.0 million and 18.5% on annual global net sales greater than $500 million. In addition, we purchased the right to receive a payment of $25.0 million, which will be payable upon the achievement of annual net sales of $250.0 million. Lorcaserin is currently in a Phase 3 clinical trial for Dravet syndrome.

Services Agreement with Arena

In October 2020, we entered into a Services Agreement with Arena (Services Agreement) under which Arena agreed to perform certain research and development services, general administrative services, management services and other mutually agreed services for us. The initial term of the Services Agreement was through December 31, 2021, and it then automatically renews for successive one-year terms. Neither party provided notice of non-renewal as of December 31, 2022. Each party may also terminate the Services Agreement for any reason, subject to specified notice periods. During 2022, we significantly reduced our activities under the Services Agreement, including as a result of our having hired employees or contracted with third parties with the requisite expertise, and we are no longer dependent on such services from Arena.

Intellectual Property

Our success depends in part on our ability to obtain and maintain proprietary protection for our product candidates and other discoveries, inventions, trade secrets and know-how that are critical to our business operations. Our success also depends in part on our ability to operate without infringing the proprietary rights of others, and in part, on our ability to prevent others from infringing our proprietary rights. A comprehensive discussion on risks relating to intellectual property is provided under the section of this prospectus entitled "Risk Factors—Risks Related to Our Intellectual Property."

As of February 1, 2023, we held an exclusive, worldwide license to issued and pending patent claims for compositions of matter and certain methods of treatment using LP352 in several jurisdictions, including issued patents in the United States, Europe (17

countries), China, Japan, India, Russia, South Korea, Australia, Mexico, New Zealand, and Israel, and pending applications in Brazil, Canada, and Macao. The terms of these patents (and applications, if issued) are capable of continuing into 2036, without taking into account any patent term adjustment or extension regimes of any country (e.g., up to five additional years in certain jurisdictions if maximum PTE or SPC applies) or any additional term of exclusivity we might obtain by virtue of later filed patent applications. For example, we exclusively license pending patent claims directed to methods of dosing LP352 in a later patent application having a term capable of continuing into 2043 in certain jurisdictions, without taking into account any applicable patent term adjustment or extension.

As of February 1, 2023, we held an exclusive, worldwide license to issued and pending patent claims for compositions of matter and certain methods of treatment using LP659 in several jurisdictions, including issued patents in the United States, Europe (39 countries), Brazil, China, Japan, Canada, Russia, South Korea, Australia, Mexico, South Africa, New Zealand, Singapore, Israel. The terms of these patents (and applications, if issued) are capable of continuing into 2029, without taking into account any patent term adjustment or extension regimes of any country (e.g., up to five additional years in certain jurisdictions if maximum PTE or SPC applies) or any additional term of exclusivity we might obtain by virtue of later filed patent applications. For example, we exclusively license patent claims for compositions of matter and certain methods of treatment using salt and crystalline forms of LP659 in several jurisdictions, including issued patents in the United States and 10 countries in Europe. The terms of these patents are capable of continuing into 2031 in certain jurisdictions, without taking into account any patent term adjustment or extension.

In addition to patent protection, we rely on trade secret protection, trademark protection and know-how to expand our proprietary position around our chemistry, technology and other discoveries and inventions that we consider important to our business. We are a party to a license agreement with Arena under which we are granted intellectual property rights to know-how that are important to our business. We have licensed know-how related to the Licensed Products (including LP352, LP659, LP143 and certain 5-HT2A compounds) in all countries around the world from Arena. The Arena License Agreement imposes various development, regulatory and/or commercial diligence obligations, payment of royalties, including a mid-single digit royalty on net sales of Licensed Products of LP352, and a low-single digit royalty on net sales of all other Licensed Products, by our company, its affiliates or its sublicensees, subject to standard reductions, and other obligations.

We also seek to protect our intellectual property by having confidentiality terms in our agreements with companies with whom we share proprietary and confidential information in the course of business discussions, and by having confidentiality terms in our agreements with our employees, consultants, scientific advisors, clinical investigators and other contractors and also by requiring our employees, commercial contractors, and certain consultants and investigators, to enter into invention assignment agreements that grant us ownership of any discoveries or inventions made by them while in our employ.

Sales and Marketing

Given our stage of development, we have not yet established a commercial organization or distribution capabilities. We intend to build a commercial infrastructure to support sales of any of our approved products. We expect to manage sales, marketing and distribution through internal resources and third-party relationships. While we may commit significant financial and management resources to commercial activities, we will also consider collaborating with one or more pharmaceutical companies to enhance our commercial capabilities.

Manufacturing

We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We currently rely, and expect to continue to rely for the foreseeable future, on third parties for the manufacturing of our product candidates for preclinical and clinical testing, as well as for commercial manufacture of any products that we may commercialize. We expect to initially obtain our supplies from manufacturers on a purchase order basis without long-term supply arrangements in place. We do not currently have arrangements in place for redundant supply for active pharmaceutical ingredients (APIs) and drug product. For all of our product candidates, we intend to identify and qualify manufacturers to provide the APIs and drug product prior to submission of an NDA to the FDA or other marketing authorization applications to other regulatory authorities.

All our product candidates are compounds of low molecular weight, generally called small molecules. They can be manufactured from readily available starting materials in reliable and reproducible processes that we expect will be amenable to scale-up and will not require specialized equipment in the manufacturing process. We expect to continue to develop product candidates that can be produced cost-effectively at contract manufacturing facilities.

Competition

The biopharmaceutical industry is characterized by rapidly advancing competition and a strong emphasis on proprietary drugs. We face competition with respect to our current product candidates and will face competition with respect to any other product

candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide.

DEEs are commonly treated with multiple combinations of AEDs though physician preference for administered therapies differs across different epilepsy types. Pharmaceutical companies, such as Lundbeck, Pfizer, and UCB have approved AEDs for the treatment of epilepsies. There are also non-pharmaceutical therapies for epilepsy patients, such as a ketogenic diet, VNS, and surgery for some patients. FINTEPLA (fenfluramine) was approved by the FDA for the treatment of seizures associated with Dravet syndrome in June 2020 and LGS in June 2022 (both include REMS programs). Epidiolex (cannabidiol) was approved by the FDA for the treatment of seizures associated with Dravet syndrome and LGS in 2018, and the treatment of seizures associated with TSC in 2020, and DIACOMIT (stiripentol) was approved by the FDA in 2018 for seizures associated with Dravet syndrome. Lorcaserin is also in a Phase 3 clinical trial for the treatment of seizures associated with Dravet syndrome. In addition, other companies are developing therapeutics for the treatment of epilepsies, including alternative approaches such as gene therapy.

In the S1P receptor modulator space, there are four drugs that have been approved by the FDA for the treatment of certain indications in multiple sclerosis: fingolimod, ozanimod, siponimod and ponesimod. There are multiple additional S1P receptor modulators in development for additional therapeutic indications beyond multiple sclerosis, including in other neurological diseases. There are also numerous other drugs and product candidates in development for indications for which we might develop our product candidates.

Additional potential competitors include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

There are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of product candidates for the treatment of the indications that we are pursuing. More established companies may have a competitive advantage over us due to their greater size, resources and institutional experience. In particular, these companies have greater experience and expertise in securing reimbursement, government contracts, relationships with key opinion leaders, conducting testing and clinical trials, obtaining and maintaining regulatory approvals and distribution relationships to market products, and marketing approved drugs. These companies also have significantly greater research and marketing capabilities than we do.

The key competitive factors affecting the success of our product candidates are likely to be their efficacy and safety, the scope and limitations of marketing approval, success of regulatory approval, successful protection of our intellectual property, and the availability of funding and reimbursement.

Other drugs, non-pharmaceutical therapies and alternative approaches to indications we may pursue for our drug candidates will compete with us both in the U.S. and elsewhere in the world.

Government Regulation and Product Approval

As a pharmaceutical company that operates in the United States, we are subject to extensive regulation. Government authorities in the United States (at the federal, state and local level) and in other countries extensively regulate, among other things, the research, development, testing, manufacturing, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of drug products such as those we are developing. Product candidates that we develop must be approved by the FDA, before they may be legally marketed in the United States and by the appropriate foreign regulatory agency before they may be legally marketed in foreign countries. Generally, our activities in other countries will be subject to regulation that is similar in nature and scope as that imposed in the United States, although there can be important differences. Additionally, some significant aspects of regulation in Europe are addressed in a centralized way, but country specific regulation remains essential in many respects.

U.S. Drug Development Process

In the United States, the FDA regulates drugs under the Federal Food, Drug and Cosmetic Act (FDCA), and its implementing regulations. A new drug must be approved by the FDA through the NDA process before it may be legally marketed in the United States. Drugs are also subject to other federal, state and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial sanctions. FDA sanctions could include, among other actions, refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters, product recalls or withdrawals from the market, product seizures, total or partial suspension of production or distribution injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. Any agency or

judicial enforcement action could have a material adverse effect on us. The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- completion of extensive preclinical laboratory tests, preclinical animal studies and formulation studies in accordance with the FDA's Good Laboratory Practice (GLP) regulations and other applicable regulations;
- performance of adequate and well-controlled human clinical trials in accordance with applicable regulations, including the FDA's good clinical practice (GCP) regulations to establish the safety and efficacy of the proposed drug for its proposed indication;
- submission to the FDA of an NDA after completion of all pivotal trials;
- a determination by the FDA within 60 days of its receipt of an NDA to file the NDA for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities where the drug is produced to assess compliance with the FDA's current good manufacturing practice (cGMP) requirements to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;
- potential FDA audit of the preclinical and/or clinical trial sites that generated the data in support of the NDA to assess compliance with GCP regulations;
- satisfactory completion of an FDA advisory committee review, if applicable; and
- FDA review and approval of the NDA prior to any commercial marketing or sale of the drug in the United States.

Before testing any compounds with potential therapeutic value in humans, the drug candidate enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies, to assess the potential safety and activity of the drug candidate. The conduct of the preclinical tests must comply with federal regulations and requirements including GLPs. The sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. An IND is a request for authorization from the FDA to administer an investigational drug product to humans. Some preclinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions regarding the proposed clinical trials and places the IND on clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA may also impose clinical holds on a drug candidate at any time before or during clinical trials due to safety concerns or non-compliance.

Clinical trials involve the administration of the drug candidate 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 GCPs, which include the requirement that all research participants 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 inclusion and exclusion criteria and the parameters 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. Further, each clinical trial must be reviewed and approved by an independent IRB at or servicing each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether 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 are also requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- Phase 1. The drug is initially administered to healthy human participants and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion, the side effects associated with increasing doses and if possible, to gain early evidence of effectiveness. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.
- Phase 2. The drug is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases or conditions and to determine dosage

tolerance, optimal dosage and dosing schedule. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.

- Phase 3. The drug is administered to an expanded patient population to further evaluate dosage and clinical efficacy at geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall benefit/risk ratio of the product and provide an adequate basis for product approval. Generally, two adequate and well-controlled Phase 3 clinical trials are required by the FDA for approval of an NDA.

Post-approval studies, or 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. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA.

During the development of a new drug, sponsors are given opportunities to meet with the FDA at certain points. These points may be prior to submission of an IND, at the end of Phase 2, and before an NDA is submitted. Meetings at other times may be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for the FDA to provide advice, and for the sponsor and the FDA to reach agreement on the next phase of development. Sponsors typically use the meetings at the end of the Phase 2 trial to discuss Phase 2 clinical results and present plans for the pivotal Phase 3 clinical trials that they believe will support approval of the new drug.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and written IND safety reports must be submitted to the FDA and the investigators for serious and unexpected AEs or any finding from tests in laboratory animals that suggests a significant risk for human participants. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA, the IRB, or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research participants or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. 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 or not 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 must also develop additional information about the chemistry and physical characteristics of the drug 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 drug candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final drug. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the drug candidate does not undergo unacceptable deterioration over its shelf life.

U.S. Review and Approval Processes

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, preclinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the drug, proposed labeling and other relevant information are submitted to the FDA as part of an NDA requesting approval to market the product. Data may come from company-sponsored clinical trials intended to test the safety and effectiveness of a use of a product, 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 effectiveness of the investigational drug product to the satisfaction of the FDA. The submission of an NDA is subject to the payment of substantial user fees; a waiver of such fees may be obtained under certain limited circumstances.

In addition, the Pediatric Research Equity Act (PREA) requires a sponsor to conduct pediatric clinical trials for most drugs, for a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration. Under PREA, original NDAs and supplements must contain a pediatric assessment unless the sponsor has received a deferral or waiver. The required assessment must evaluate the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The sponsor or FDA may request a deferral of pediatric clinical trials for some or all of the pediatric subpopulations. A deferral may be granted for several reasons, including a finding that the drug is ready for approval for use in adults before pediatric clinical trials are complete or that additional safety or effectiveness data need to be collected before the pediatric clinical trials begin. The FDA must send a non-compliance letter to any sponsor that fails to submit the required assessment, keep a deferral current or fails to submit a request for approval of a pediatric formulation. Unless otherwise required by regulation, the PREA does not apply to any drug for an indication for which orphan designation has been granted. However, if only one indication for a product has orphan designation, a pediatric assessment may still be required for any applications to market that same product for the non-orphan indication(s).

The FDA reviews all NDAs submitted before it accepts them for filing and may request additional information rather than accepting an NDA for filing. The FDA must make a decision on accepting an NDA for filing within 60 days of receipt. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. Under the Prescription Drug User Fee Act (PDUFA) guidelines that are currently in effect, the FDA has a goal of ten months from the date of "filing" of a standard NDA for a new molecular entity to review and act on the submission. This review typically takes twelve months from the date the NDA is submitted to FDA because the FDA has approximately two months to make a "filing" decision after the application is submitted. The FDA does not always meet its PDUFA goal dates for standard and priority NDAs, and the review process is often significantly extended by FDA requests for additional information or clarification.

After the NDA submission is accepted for filing, the FDA reviews the NDA to determine, among other things, whether the proposed product is safe and effective for its intended use and whether the product is being manufactured in accordance with cGMP to assure and preserve the product's identity, strength, quality and purity. The FDA may refer applications for novel drug products or drug 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. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions and typically follows the advisory committee's recommendations.

Before approving an NDA, the FDA will inspect the facilities at which the product is manufactured. 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. Additionally, before approving an NDA, the FDA may inspect one or more clinical sites to assure compliance with GCP requirements. After the FDA evaluates the application, manufacturing process and manufacturing facilities, it may issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application has ended and the application will not be approved in its present form. A Complete Response Letter usually describes all of the specific deficiencies in the NDA identified by the FDA. The Complete Response Letter may detail required additional clinical data and/or (an) additional pivotal Phase 3 clinical trial(s), and/or other significant and time-consuming requirements related to clinical trials, preclinical studies or manufacturing. If a Complete Response Letter is issued, the applicant may either resubmit the NDA, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if such data and information are submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling or may condition the approval of the NDA on other changes to the proposed labeling, development of adequate controls and specifications, or a commitment to conduct one or more post-market studies or clinical trials. For example, the FDA may require Phase 4 testing, which involves clinical trials designed to further assess a drug safety and effectiveness, and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized. The FDA may also determine that a REMS is necessary to assure the safe use of the drug. If the FDA concludes a REMS is needed, the sponsor of the NDA must submit a proposed REMS; the FDA will not approve the NDA without an approved REMS, if required. A REMS could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug 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, if it affects more than 200,000 individuals in the United States, there is no reasonable expectation that the cost of developing and making a drug product available in the United States for this type of disease or condition will be recovered from sales of the product. Orphan designation must be requested before submitting an NDA. After the FDA grants orphan designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications to market the same drug or biological product for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity or inability to manufacture the product in sufficient quantities. The designation of such drug also entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. Competitors, however, may receive approval of different products for the indication for which the orphan product has exclusivity or obtain approval for the same product but for a different indication for which

the orphan product has exclusivity. If an orphan designated product receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan exclusivity.

Expedited Development and Review Programs

The FDA has a fast track designation program that is intended to expedite or facilitate the process for reviewing new drug products that meet certain criteria. Specifically, new drugs are eligible for Fast Track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a fast track product has opportunities for more frequent interactions with the applicable FDA review team during product development and, once an NDA is submitted, the product candidate may be eligible for priority review. With regard to a fast track product, the FDA may consider for review sections of the NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA.

Any product submitted to the FDA for approval, including a product with a fast track designation, may also be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. A product is eligible for priority review if it is designed to treat a serious condition, and if approved, would provide a significant improvement in the treatment, diagnosis or prevention of a serious condition compared to marketed products. The FDA will attempt to direct additional resources to the evaluation of an application for a new drug designated for priority review in an effort to facilitate the review. The FDA endeavors to review applications with priority review designations within six months of the filing date as compared to ten months for review of new molecular entity NDAs under its current PDUFA review goals.

In addition, a product may be eligible for accelerated approval. Drug products intended to treat serious or life-threatening diseases or conditions may be eligible for accelerated approval upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require that a sponsor of a drug receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials to verify the predicted clinical benefit. Products receiving accelerated approval may be subject to expedited withdrawal procedures if the sponsor fails to conduct the required clinical trials, or if such trials fail to verify the predicted clinical benefit. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

A sponsor may seek FDA designation of a drug candidate as a “breakthrough therapy” if the drug is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. If a drug is designated as breakthrough therapy, FDA will expedite the development and review of such drug. Breakthrough therapy designation includes all of the fast track program features, as well as more intensive FDA interaction and guidance. The breakthrough therapy designation is a distinct status from both accelerated approval and priority review, which can also be granted to the same drug if relevant criteria are met.

Fast track designation, priority review, accelerated approval and breakthrough therapy designation do not change the standards for approval but may expedite the development or approval process. Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. In addition, such designations or shortened review periods may not provide a material commercial advantage.

Post-Approval Requirements

Any drug products manufactured or distributed pursuant to FDA approvals are subject to continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse experiences with the product, providing the FDA with updated safety and efficacy information, product sampling and distribution requirements, and complying with FDA promotion and advertising requirements. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing, annual program fees for any marketed products.

In addition, quality control and manufacturing procedures must continue to conform to applicable manufacturing requirements after approval to ensure the long-term stability of the drug product. cGMP regulations require among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are

required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. In addition, changes to the manufacturing process are strictly regulated, and depending on the significance of the change, may require prior FDA approval before being implemented. Other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including AEs 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 studies to assess new safety risks, or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters, or untitled letters;
- clinical holds on clinical studies;
- refusal of the FDA to approve pending 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 products;
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs;
- mandated modification of promotional materials and labeling and the issuance of corrective information;
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases and other communications containing warnings or other safety information about the product; or
- injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising and promotion of drug products. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe, in their independent professional medical judgment, legally available products for uses that are not described in the product's labeling and that differ from those tested and approved by the FDA. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products. The federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined companies from engaging in off-label promotion. The FDA and other regulatory agencies have also required that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. However, companies may share truthful and not misleading information that is otherwise consistent with a product's FDA-approved labeling.

U.S. Patent Term Restoration and Marketing Exclusivity

Depending upon the timing, duration and specifics of the FDA approval of the use of our product candidates, some of our U.S. patents, if granted, may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years, as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of an NDA plus the time between the submission date of an NDA and the approval of that application. Only one patent applicable to an approved drug is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The U.S. Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term

extension or restoration. In the future, we may intend to apply for restoration of patent term for one of our currently owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant NDA.

Market exclusivity provisions under the FDCA can also delay the submission or the approval of certain marketing applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to obtain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not approve or even accept for review an abbreviated new drug application (ANDA) or a 505(b)(2) NDA submitted by another company for another drug based on the same active moiety, regardless of whether the drug is intended for the same indication as the original innovative drug or for another indication, where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement to one of the patents listed with the FDA by the innovator NDA holder. The FDCA alternatively provides three years of marketing exclusivity for an NDA, or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the modification for which the drug received approval on the basis of the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the active agent for the original indication or condition of use. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Orphan drug exclusivity, as described above, may offer a seven-year period of marketing exclusivity, except in certain circumstances. Pediatric exclusivity is another type of non-patent 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 trial in accordance with an FDA-issued "Written Request" for such a trial.

DEA Regulation

The CSA establishes registration, security, recordkeeping, reporting, storage, distribution and other requirements administered by the DEA. The DEA is concerned with the control of handlers of controlled substances, and with the equipment and raw materials used in their manufacture and packaging, in order to prevent loss and diversion into illicit channels of commerce. The DEA regulates controlled substances as Schedule I, II, III, IV or V substances.

Schedule I substances by definition have no established medicinal use, and may not be marketed or sold in the United States. A pharmaceutical product may be listed as Schedule II, III, IV or V, with Schedule II substances considered to present the highest risk of abuse and Schedule V substances the lowest relative risk of abuse among such substances.

Annual registration is required for any facility that manufactures, distributes, dispenses, imports or exports any controlled substance. The registration is specific to the particular location, activity and controlled substance schedule. For example, separate registrations are needed for import and manufacturing, and each registration will specify which schedules of controlled substances are authorized. The DEA typically inspects a facility to review its security measures prior to issuing a registration. Security requirements vary by controlled substance schedule, with the most stringent requirements applying to Schedule I and Schedule II substances. Required security measures include background checks on employees and physical control of inventory through measures such as cages, surveillance cameras and inventory reconciliations. Records must be maintained for the handling of all controlled substances, and periodic reports made to the DEA. Reports must also be made for thefts or losses of any controlled substance, and authorization must be obtained to destroy any controlled substance. In addition, special authorization and notification requirements apply to imports and exports.

To meet its responsibilities, the DEA conducts periodic inspections of registered establishments that handle controlled substances. Failure to maintain compliance with applicable requirements, particularly as manifested in loss or diversion, can result in enforcement action that could have a material adverse effect on our business, results of operations and financial condition. The DEA may seek civil penalties, refuse to renew necessary registrations, or initiate proceedings to revoke those registrations. In certain circumstances, violations could eventuate in criminal proceedings. Individual states also regulate controlled substances, and we and our contract manufacturers will be subject to state regulation on distribution of these products.

Other U.S. Healthcare Laws and Compliance Requirements

Although we currently do not have any products on the market, we are and, upon approval and commercialization, will be subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which we conduct our business. In the United States, such laws include, without limitation, state and federal anti-kickback, fraud and abuse, false claims, privacy and security, price reporting, and physician sunshine laws and regulations.

The federal Anti-Kickback Statute prohibits, among other things, any person or entity, from knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any item or service reimbursable under Medicare, Medicaid or other federal healthcare programs. The term remuneration has been interpreted broadly to include anything of value. 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. The exceptions and safe harbors are drawn narrowly and practices that involve remuneration that may be alleged to be intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Our practices may not in all cases meet all of the criteria for protection under a statutory exception or regulatory safe harbor.

Additionally, 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 false claims laws, including the False Claims Act, which prohibit, among other things, any person or entity from knowingly presenting, or causing to be presented, a false 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 material to a false or fraudulent claim to the federal government. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim under the False Claims Act includes "any request or demand" for money or property presented to the U.S. government. The federal civil False Claims Act can be enforced through private "qui tam" actions brought by individual whistleblowers in the name of the government. In addition, manufacturers can be held liable under the civil False Claims Act even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. Pharmaceutical and other healthcare companies have been prosecuted under these laws for, among other things, allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product and for causing false claims to be submitted because of the companies' marketing of the product for unapproved, and thus non-covered, uses. In addition, a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act.

The federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) also created new federal criminal statutes that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any money or property owned by, or under the control or custody of, any healthcare benefit program, including private third-party payors and knowingly and willfully falsifying, concealing or covering up by trick, scheme or device, a material fact or making any materially false, fictitious or fraudulent 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. Also, many states have similar fraud and abuse statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

Additionally, the federal Physician Payments Sunshine Act, and its implementing regulations, require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) annually report information related to certain payments or other transfers of value made or distributed to physicians (currently defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals, and certain ownership and investment interests held by physicians and their immediate family members.

Numerous state, federal and foreign laws, self-regulatory schemes, regulations, and standards govern the collection of, disclosure of, use of, access to, transfer of, and confidentiality and security of personal information and health-related information, and could apply now or in the future to our operations or the operations of our partners. For example, In the United States, numerous federal and state laws and regulations, including data breach notification laws, health information privacy laws, and federal and state consumer protection laws and regulations (e.g., Section 5 of the FTC Act), that govern the collection, use, disclosure, and protection of health-related and other personal information could apply to our operations or the operations of our partners. For example, HIPAA, as amended by Health Information Technology for Economic and Clinical Health Act (HITECH) and regulations implemented

thereunder, imposes requirements relating to the privacy, security and transmission of individually identifiable health information on covered entities, including certain healthcare providers, health plans, and healthcare clearinghouses, and their respective "business associates" that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, as well as their covered subcontractors. Entities that are found to be in violation of HIPAA as the result of a breach of unsecured protected health information, a complaint about privacy practices or an audit by complaint about privacy practices or an audit by the Department of Health and Human Services (HHS), may be subject to significant civil, criminal and administrative fines and penalties and/or additional reporting and oversight obligations if required to enter into a resolution agreement and corrective action plan with HHS to settle allegations of HIPAA non-compliance. Further, entities that knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA covered entity in a manner that is not authorized or permitted by HIPAA may be subject to criminal penalties.

In addition, state laws govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. For instance, California enacted the California Consumer Privacy Act (CCPA) in January 2020. The CCPA creates new individual privacy rights for California consumers (as defined in the law) and places increased privacy and security obligations on entities handling certain personal information of consumers or households. The CCPA, among other things, creates new data privacy obligations for covered companies and provides new privacy rights to California residents, including the right to access and delete their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA also creates a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach. Further, a new privacy law, the California Privacy Rights Act (CPRA) went into effect on January 1, 2023 and modifies significantly the CCPA. Both the CCPA and CPRA could impact our business activities depending on how they are interpreted and exemplifies the vulnerability of our business to not only cyber threats but also the evolving regulatory environment related to personal data and protected health information. In addition to California, other states in which we have, or may have in the future, employees or operations, have passed or may pass privacy laws. For example, Virginia, Colorado, Connecticut, and Utah have passed privacy laws that go into effect in 2023, but aspects of these state privacy statutes remain unclear, resulting in further legal uncertainty and potentially requiring us to modify our data practices and policies and to incur substantial additional costs and expenses in an effort to comply.

We also are or will become subject to applicable privacy laws in the jurisdictions in which we are established or in which we sell or market our products or run clinical trials. For example, if we conduct EU-based clinical trials, we will be subject to the GDPR in relation to our collection, control, processing and other use of personal data of data participants within the European Economic Area (EEA) (i.e. data relating to an identifiable living individual) including the health and medical information of clinical trial participants. The GDPR is directly applicable in each EU and EEA Member State, however, it provides that EU and EEA Member States may introduce further conditions, including limitations which could limit our ability to collect, use and share personal data (including health and medical information), or could cause our compliance costs to increase, ultimately having an adverse impact on our business. The GDPR imposes onerous accountability obligations requiring data controllers and processors to maintain a record of their data processing activities and implement policies as part of its mandated privacy governance framework. It also requires data controllers to be transparent and disclose to data participants (in a concise, intelligible and easily accessible form) how their personal data is to be used, imposes limitations on retention of personal data; defines for the first time pseudonymized (i.e., key-coded) data; introduces mandatory data breach notification requirements; and sets higher standards for data controllers to demonstrate that they have obtained valid consent for certain data processing activities. We are also subject to EU rules with respect to cross-border transfers of personal data out of the EU and EEA. We are subject to the supervision of local data protection authorities in those EU jurisdictions where we are established or otherwise subject to the GDPR, and may also be subject to the laws of other jurisdictions, such as Switzerland, which may have their own set of stringent privacy and data protection laws and regulations. For example, the Swiss Federal Act on Data Protection (DPA) applies to the collection and processing of personal data, including health-related information, in certain circumstances, for companies conducting business in Switzerland or with Swiss companies or individuals. The DPA has been revised and adopted by the Swiss Parliament, and the revised law may result in an increase of costs of compliance, risks of noncompliance and penalties for noncompliance. Fines for certain breaches of the GDPR are significant: up to the greater of €20 million or 4% of total global annual turnover. In addition to the foregoing, a breach of the GDPR or other applicable privacy and data protection laws and regulations could result in regulatory investigations, reputational damage, orders to cease/change our use of data, enforcement notices, or potential civil claims including class action type litigation.

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 United Kingdom (UK) have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it believes are inadequate. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA and UK's standard contractual clauses, these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to

lawfully transfer personal data to the United States. If there is no lawful manner for us to transfer personal data from the EEA, the UK, or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Some European regulators have prevented companies from transferring personal data out of Europe for allegedly violating the GDPR's cross-border data transfer limitations.

In order to distribute products commercially, we must comply with state laws that require the registration of manufacturers and wholesale distributors of pharmaceutical products in a state, including, in certain states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Some states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to adopt new technology capable of tracking and tracing product as it moves through the distribution chain. Several states have enacted legislation requiring pharmaceutical companies to establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, track and report gifts, compensation and other remuneration made to physicians and other healthcare providers, clinical trials and other activities, and/or register their sales representatives, as well as to prohibit pharmacies and other healthcare entities from providing certain physician prescribing data to pharmaceutical companies for use in sales and marketing, and to prohibit certain other sales and marketing practices. All of our activities are also potentially subject to federal and state consumer protection and unfair competition laws.

If our operations are found to be in violation of any of the federal and state healthcare laws described above or any other governmental regulations that apply to us, we may be subject to significant penalties, including without limitation, civil, criminal and/or administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government programs, such as Medicare and Medicaid, injunctions, private "qui tam" actions brought by individual whistleblowers in the name of the government, or refusal to allow us to enter into government contracts, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Pharmaceutical Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we or our collaborators obtain regulatory approval. In the United States and markets in other countries, sales of any products for which we receive regulatory approval for commercial sale will depend, in part, on the extent to which third-party payors provide coverage, and establish adequate reimbursement levels for such drug products.

In the United States, third-party payors include federal and state healthcare programs, government authorities, private managed care providers, private health insurers and other organizations. Third-party payors are increasingly challenging the price, examining the medical necessity and reviewing the cost-effectiveness of medical drug products and medical services, in addition to questioning their safety and efficacy. Such payors may limit coverage to specific drug products on an approved list, also known as a formulary, which might not include all of the FDA-approved drugs for a particular indication. We or our collaborators may need to conduct expensive pharmaco-economic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain the FDA approvals. Nonetheless, our product candidates may not be considered medically necessary or cost-effective. Moreover, the process for determining whether a third-party payor will provide coverage for a drug product may be separate from the process for setting the price of a drug product or for establishing the reimbursement rate that such a payor will pay for the drug product. A payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Further, no uniform policy for coverage and reimbursement exists in the United States, and coverage and reimbursement can differ significantly from payor to payor. As a result, one payor's determination to provide coverage for a drug product does not assure that other payors will also provide coverage for the drug product. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

If we elect to participate in certain governmental programs, we may be required to participate in discount and rebate programs, which may result in prices for our future products that will likely be lower than the prices we might otherwise obtain. For example, drug manufacturers participating under the Medicaid Drug Rebate Program must pay rebates on prescription drugs to state Medicaid programs.

Different pricing and reimbursement schemes exist in other countries. In the EU, governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national health care systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these

countries may require the completion of clinical trials that compare the cost-effectiveness of a particular drug candidate to currently available therapies. Other member states allow companies to fix their own prices for medicines, but monitor and control company profits. The downward pressure on health care costs in general, particularly prescription drugs, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country.

The marketability of any product candidates for which we or our collaborators receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, emphasis on managed care in the United States has increased and we expect will continue to increase the pressure on pharmaceutical pricing. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we or our collaborators receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Healthcare Reform

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medical products and services, implementing reductions in Medicare and other healthcare funding and applying new payment methodologies.

For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively ACA), was enacted, which affected existing government healthcare programs and resulted in the development of new programs. There have been judicial and Congressional challenges to certain aspects of the ACA, and it is unclear how such litigation and other efforts to challenge, repeal or replace the ACA will impact the ACA or our business. In addition, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 (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 creating a new manufacturer discount program.

Other legislative changes relating to healthcare have also been proposed and adopted in the United States since the ACA was enacted, and there has been heightened governmental scrutiny recently over the manner in which pharmaceutical companies set prices for their marketed products, which has resulted in several Congressional inquiries, presidential executive orders, and proposed federal legislation, as well as state efforts, designed to, among other things, bring more transparency to product pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. For example, the IRA also, among other things, (1) directs HHS to negotiate the price of certain single-source drugs and biologics covered under Medicare and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions will take effect progressively starting in fiscal year 2023. The IRA is likely to have a significant impact on the pharmaceutical industry.

We anticipate that these new laws will result in additional downward pressure on coverage and the price that we receive for any approved product, and could seriously harm our business. Any reduction in reimbursement from Medicare and 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 products. In addition, it is possible that there will be further legislation or regulation that could harm our business, financial condition, and results of operations.

The U.S. Foreign Corrupt Practices Act

The U.S. Foreign Corrupt Practices Act of 1977 (FCPA) prohibits any U.S. individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Europe / Rest of World Government Regulation

In addition to regulations in the United States, we will be subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our products. Whether or not we or our potential collaborators obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the

United States have a similar process that requires the submission of an application for a clinical trial authorization (CTA) much like the IND prior to the commencement of human clinical trials. In the EU, for example, a CTA must be submitted to each country's national health authority and an application made to an independent ethics committee, much like the FDA and IRB, respectively. Once the CTA is approved in accordance with a country's requirements and a favorable ethics committee opinion has been issued, clinical trial development may proceed.

The requirements and process governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, the clinical trials are conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

To obtain regulatory approval of an investigational drug or biological product under EU regulatory systems, we must submit a marketing authorization application either under the so-called centralized or national authorization procedures.

Centralized procedure. The centralized procedure provides for the grant of a single marketing authorization by the European Commission following a favorable opinion by the EMA that is valid in all EU member states, as well as Iceland, Liechtenstein and Norway. The centralized procedure is compulsory for medicines produced by specified biotechnological processes, products designated as orphan medicinal products, and products with a new active substance indicated for the treatment of specified diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative disorders or autoimmune diseases, other immune dysfunctions and viral diseases. The centralized procedure is optional for other products that represent a significant therapeutic, scientific or technical innovation, or whose authorization would be in the interest of public health or which contain a new active substance for indications other than those specified to be compulsory.

National authorization procedures. There are also two other possible routes to authorize medicinal products in several EU countries, which are available for investigational medicinal products that fall outside the scope of the centralized procedure:

- Decentralized procedure. Using the decentralized procedure, an applicant may apply for simultaneous authorizations in more than one EU Member State of medicinal products that have not yet been authorized in any EU Member State and that do not fall within the mandatory scope of the centralized procedure.

- Mutual recognition procedure. In the mutual recognition procedure, a medicine is first authorized in one EU Member State, in accordance with the national procedures of that country. Following this, further marketing authorizations can be sought from other EU countries in a procedure whereby the countries concerned agree to recognize the validity of the original, national marketing authorization.

The EMA grants orphan drug designation to promote the development of products for the treatment, prevention or diagnosis of life-threatening or chronically debilitating conditions affecting not more than five in 10,000 people in the EU. In addition, orphan drug designation can be granted if the drug is intended for a life threatening or chronically debilitating condition in the EU and without incentives it is unlikely that sales of the drug in the EU would be sufficient to justify the investment required to develop the drug. Orphan drug designation is only available if there is no other satisfactory method approved in the EU of diagnosing, preventing or treating the condition, or if such a method exists, the proposed orphan drug will be of significant benefit to patients. Orphan drug designation provides opportunities for free or reduced-fee protocol assistance, fee reductions for marketing authorization applications and other post-authorization activities and ten years of market exclusivity following drug approval, which can be extended to 12 years if trials are conducted in accordance with an agreed-upon pediatric investigational plan. The exclusivity period may be reduced to six years if the designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity.

For other countries outside of the EU, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, again, the clinical trials are conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

If we or our potential collaborators fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Human Capital and Employee Engagement

We believe that our success largely depends upon attracting and retaining a highly skilled team with key expertise in our areas of therapeutic focus. We are committed to creating and maintaining a culture that is positive, diverse, inclusive and dynamic. Our human capital priorities include, as applicable, identifying, recruiting, retaining, incentivizing, developing and integrating our existing and

future employees. We provide our employees competitive base salaries, as well as a cash target bonus, a robust benefits package and equity compensation. In addition, we regularly conduct an employee survey to gauge employee engagement and identify areas of potential improvement.

As of December 31, 2022, we employed 33 employees, 32 of whom are full-time, consisting of clinical, research and manufacturing, operations, finance and business personnel. Fifteen of our employees hold either an M.D. or Ph.D. degree. None of our employees are subject to a collective bargaining agreement. We consider our relationship with our employees to be good.

Facilities

We entered into a two-year lease for certain office space in La Jolla, California in June 2021. Rent payments were approximately $29,000 per month for the first year and increased by 4.5% in July 2022. In August 2022, we extended the lease agreement (lease extension) through December 31, 2024. Rent payments under the lease extension are approximately $33,000 starting in July 2023 and increase by 4.5% in July 2024. We believe that our existing facilities are adequate to meet our current needs, and that suitable additional alternative spaces will be available in the future on commercially reasonable terms.

Legal Proceedings

We are currently not a party to any material legal proceedings.

Item 1A. Risk Factors.

An investment in shares of our common stock is speculative and involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this Annual Report, including our audited financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations" before deciding whether to purchase, hold or sell shares of our common stock. The occurrence of any of the risks described below could harm our business, financial condition, results of operations, growth prospects and/or stock price or cause our actual results to differ materially from those contained in forward-looking statements we have made in this Annual Report and those we may make from time to time. You should consider all of the risk factors described when evaluating our business. Any of the risks identified herein relating to Arena are also risks relating to Pfizer.

Risks Related to Our Limited Operating History, Financial Position and Need For Additional Capital

We have a limited operating history, and we have incurred losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future. We may never generate any revenue or become profitable or, if we achieve profitability, we may not be able to sustain it.

We were incorporated in January 2020 and we have a limited operating history upon which you can evaluate our business and prospects. Our operations to date have been primarily focused on organizing and staffing our company, research and development activities, business planning, raising capital, in-licensing intellectual property rights and establishing our intellectual property portfolio, and providing general and administrative support for these operations. LP352, our most advanced product candidate, is in early clinical development, while our other product candidates, including LP659, are in the preclinical or research stage. We have not yet demonstrated an ability to overcome many of the risks and uncertainties frequently encountered by companies in the biopharmaceutical industry, including an ability to obtain regulatory approval of a product candidate, manufacture any product candidate at commercial scale, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. In addition, we have limited experience completing clinical trials as a company. Consequently, any predictions about our future performance may not be as accurate as they would be if we had a history of successfully developing and commercializing biopharmaceutical products.

Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effectiveness in the targeted indication or an acceptable safety profile, gain regulatory approval and become commercially viable. We have no products approved for commercial sale and have not generated any revenue to date, and we continue to incur significant research and development and other expenses related to our ongoing operations. As a result, we are not profitable and have incurred net losses since our inception in January 2020. For the years ended December 31, 2022 and 2021, we reported net losses of $43.9 million and $27.8 million, respectively. As of December 31, 2022, we had an accumulated deficit of $86.1 million.

We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase as we:

- continue to invest in our research and development activities, including conducting preclinical studies;

- submit INDs and conduct clinical trials for our current and future product candidates;
- hire additional personnel and build our internal resources, including those related to audit, patent, other legal, regulatory and tax-related services associated with maintaining compliance with exchange listing and Securities and Exchange Commission (SEC) requirements, director and officer insurance premiums and investor and public relations costs;
- obtain, expand, maintain, enforce and protect our intellectual property portfolio;
- operate as a public company;
- seek marketing approvals for any product candidates that successfully complete the clinical trial process; and
- establish a sales, marketing and distribution infrastructure and establish manufacturing capabilities, whether alone or with third parties, to commercialize product candidates for which we may obtain regulatory approval, if any.

To become and remain profitable, we must succeed in developing and eventually commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing clinical trials and preclinical studies of our product candidates, obtaining regulatory approval for these product candidates and manufacturing, marketing and selling any products for which we may obtain regulatory approval. We are only in the preliminary stages of most of these activities. We may never succeed in these activities and, even if we do, may never generate revenues that are significant enough to achieve profitability. We may 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. Because of the numerous risks and uncertainties associated with biopharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product candidates or even continue our operations. Our prior net losses and expected future net losses have had and will continue to have an adverse effect on our stockholders' equity and working capital. A decline in the value of our company could also cause you to lose all or part of your investment.

We will need substantial additional capital to finance our operations, which may not be available on acceptable terms, or at all. The effects of macroeconomic conditions and geopolitical events, including economic slowdowns, recessions, inflation, rising interest rates and tightening of credit markets caused by COVID-19 or another pandemic, the conflict in Ukraine or otherwise, may limit our access to capital. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate certain of our product development efforts or other operations.

We expect our expenses to increase substantially in connection with our ongoing and planned activities, particularly as we continue to develop our product candidates in preclinical studies and clinical trials and expand our organization by hiring additional personnel. Our expenses will increase substantially if our product candidates successfully complete early clinical and other studies, and also could increase beyond expectations if the U.S. Food and Drug Administration (FDA) or other regulatory authorities require us to perform clinical and other studies in addition to those that we currently anticipate. In addition, we have incurred and expect to continue to incur additional costs associated with operating as a public company. Furthermore, if we obtain marketing approval for our product candidates, we expect to incur significant expenses related to manufacturing, marketing, sales and distribution.

As of December 31, 2022, our cash, cash equivalents and short-term investments were $67.6 million. We believe, based on our current operating plan, that our existing cash, cash equivalents and short-term investments, along with proceeds from the follow-on public offering completed in February 2023, will be sufficient to fund our operations for at least the next 12 months. However, our operating plan may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings, third-party funding, marketing and distribution arrangements, as well as other collaborations, strategic alliances and licensing arrangements, or any combination of these approaches.

In any event, we will require substantial additional capital to support our business operations as we pursue additional preclinical and clinical activities and regulatory approval of our current or any future product candidates, and otherwise to support our continuing operations. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. Even if we believe we have sufficient capital for our current or future operating plans, we may seek additional capital if market conditions are favorable or if we have specific strategic considerations. Any additional capital raising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and, if approved, commercialize our current and any future product candidates.

Additional funding may not be available on acceptable terms, or at all. As a result of adverse geopolitical and macroeconomic developments, such as the COVID-19 pandemic and actions taken to slow its spread, the ongoing conflict between Ukraine and Russia and related sanctions, and global supply chain challenges, the global credit and financial markets have experienced extreme volatility

and disruptions, including severely diminished liquidity and credit availability, high inflation rates and the responses by central banking authorities to control such inflation, declines in consumer confidence, declines in economic growth, increases in unemployment rates, and uncertainty regarding economic stability. If the equity and credit markets deteriorate or are otherwise not favorable, it may make any necessary debt or equity financing more difficult, more costly or more dilutive. If we do not raise additional capital in sufficient amounts, we may be prevented from pursuing development and commercialization efforts, which would adversely affect our business, results of operations, financial condition and prospects.

Raising additional capital or acquiring or licensing assets by issuing equity or debt securities may cause dilution to our stockholders and raising funds through lending and licensing arrangements may restrict our operations or require us to relinquish proprietary rights.

We may seek additional capital through a combination of public and private equity offerings, debt financings, strategic partnerships and alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a stockholder. The incurrence of indebtedness would result in increased fixed payment obligations and could involve certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we raise additional capital through future collaborations, strategic alliances or third-party licensing arrangements, we may have to relinquish valuable 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 additional capital when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts, or grant rights to develop and market product candidates that we would otherwise develop and market ourselves.

Unfavorable geopolitical and macroeconomic developments could adversely affect our business, financial condition or results of operations.

From time to time we may maintain a portfolio of investments in marketable debt securities, which are recorded at fair value. Although we have established investment guidelines relative to diversification and maturity with the objectives of maintaining safety of principal and liquidity, we rely on credit rating agencies to help evaluate the riskiness of investments, and such agencies may not accurately predict such risk. In addition, such agencies may reduce the credit quality of our individual holdings, which could adversely affect their value. Lower credit quality and other market events, such as changes in interest rates and deterioration in credit markets, may have an adverse effect on the fair value of our investment holdings and cash position.

Our business could be adversely affected by conditions in the U.S. and global economies, the United States and global financial markets and adverse geopolitical and macroeconomic developments, including the ongoing COVID-19 pandemic and the conflict between Ukraine and Russia and related sanctions. For example, inflation rates, particularly in the United States, have increased recently to levels not seen in years, and increased inflation may result in increases in our operating costs (including our labor costs), reduced liquidity and limits on our ability to access credit or otherwise raise capital on acceptable terms, if at all. In response to rising inflation, the U.S. Federal Reserve has raised, and may again raise, interest rates, which, coupled with reduced government spending and volatility in financial markets, may have the effect of further increasing economic uncertainty and heightening these risks. A weak or declining economy could also strain our suppliers and manufacturers, possibly resulting in supply disruption. Any of the foregoing could harm our business.

Additionally, financial markets around the world experienced volatility following the invasion of Ukraine by Russia in February 2022, including as a result of economic sanctions and export controls against Russia and countermeasures taken by Russia. The full economic and social impact of these sanctions and countermeasures, in addition to the ongoing military conflict between Ukraine and Russia, which could conceivably expand, remains uncertain; however, both the conflict and related sanctions have resulted and could continue to result in disruptions to trade, commerce, pricing stability, credit availability, and/or supply chain continuity, in both Europe and globally, and has introduced significant uncertainty into global markets. While we do not currently operate in Russia, Ukraine or Eastern Europe, as the adverse effects of this conflict continue to develop our business and results of operations may be adversely affected.

Risks Related to the Development and Commercialization of Our Product Candidates

We are early in our development efforts and have only one product candidate, LP352, in early clinical development. All of our other product candidates are in the preclinical or research stage. If we are unable to advance our product candidates in clinical

development, obtain regulatory approval and ultimately commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed.

We are in the early stages of our development efforts and have one product candidate, LP352, in clinical development. We have completed the SAD and MAD portions of a Phase 1 clinical trial and are currently conducting the PACIFIC Study, a Phase 1b/2a clinical trial for this product candidate. Our other product candidates currently in development, including LP659, are in the preclinical stage. We will need to progress LP659 and any other early product candidates through IND-enabling studies and submit INDs to the FDA prior to initiating their clinical development. Moreover, none of our product candidates have advanced into a pivotal study. Our ability to generate product revenues, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of our product candidates. The success of our product candidates will depend on several factors, including the following:

- successful enrollment in clinical trials and completion of clinical trials and preclinical studies with favorable results;
- clearance of INDs by the FDA or similar regulatory filings by comparable foreign regulatory authorities for the conduct of clinical trials of our product candidates and our proposed design of future clinical trials;
- demonstrating the safety and efficacy of our product candidates to the satisfaction of applicable regulatory authorities;
- the effect of recent or potential health care legislation in the United States and European Union;
- receipt of marketing approvals from applicable regulatory authorities, including NDAs from the FDA and maintaining such approvals;
- making arrangements with third-party manufacturers for, or establishing, clinical and commercial manufacturing capabilities;
- establishing sales, marketing and distribution capabilities and launching commercial sales of our products, if and when approved, whether alone or in collaboration with others;
- establishing and maintaining of patent and trade secret protection or regulatory exclusivity for our product candidates;
- our ongoing relationship with Pfizer, from whom we license our product candidates, including LP352 and LP659;
- maintaining an acceptable safety profile of our products following approval;
- the availability of adequate reimbursement for our products following approval;
- acceptance by physicians, payors and patients of the benefits, safety and efficacy of our products following approval; and
- building and maintaining an organization of people who can successfully develop, sell and distribute our product candidates.

The success of our business, including our ability to finance our company and generate any revenue in the future, will primarily depend on the successful development, regulatory approval and commercialization of our most advanced product candidate, LP352, as well as our other product candidates, which may never occur. We have not yet succeeded and may not succeed in demonstrating efficacy and safety for any product candidates in clinical trials or in obtaining marketing approval thereafter. Given our early stage of development, it will take several years before we can demonstrate the safety and efficacy of a treatment sufficient to warrant approval for commercialization, if we can do so at all. If we are unable to develop, or obtain regulatory approval for, or, if approved, successfully commercialize our product candidates, we may not be able to generate sufficient revenue to continue our business.

Risks associated with the in-licensing or acquisition of product candidates could cause substantial delays in the preclinical and clinical development of our product candidates.

Prior to October 2020, we had no involvement with or control over the preclinical and early clinical research and development of our product candidates. We have relied on third parties, including Arena, to have conducted such research and development in accordance with the applicable protocol, legal, regulatory and scientific standards prior to the in-licensing of our product candidates. If the research and development processes or the results of the development programs prior to the in-licensing of our product candidates prove to be unreliable, this could result in increased costs and delays in the development of our product candidates, which could adversely affect any future revenue from these product candidates.

We have licensed our product candidates from Arena. The fields of the licenses for these product candidates contain certain restrictions. For example, the field of license for LP659 is for developmental, degenerative and autoimmune disease, disorders or conditions of the CNS or peripheral nervous system. We also rely on Arena to help protect the intellectual property rights relating to our licensed product candidates. The scope of our license or Arena's failure to cooperate with us to protect our intellectual property

could have an adverse impact on our ability to develop our product candidates and could limit our ability to successfully commercialize our product candidates.

We may also acquire or in-license additional product candidates for preclinical or clinical development in the future as we continue to build our pipeline. The risks associated with acquiring or in-licensing current or future product candidates could result in delays in the commencement or completion of our research and development, prevent or impede our commercialization, and adversely affect or delay our ability to generate revenues from our product candidates.

Clinical and preclinical drug development involves a lengthy and expensive process with an uncertain outcome. The results of prior clinical trials and early preclinical studies and clinical trials of our product candidates are not necessarily predictive of future results.

Before we can initiate clinical trials for our product candidates, we must submit the results of preclinical studies to the FDA, European Medicines Agency (EMA) or comparable regulatory authorities along with other information, including information about product candidate chemistry, manufacturing and controls, and our proposed clinical trial protocol, as part of an IND application or similar regulatory filing. Before obtaining marketing approval from the FDA, EMA or other comparable foreign regulatory authorities for the sale of our product candidates, we must complete preclinical development and extensive clinical trials to demonstrate the safety and efficacy of our product candidates. Clinical and preclinical drug development is expensive and can take many years to complete, and its outcome is inherently uncertain. Our clinical trials may not be conducted as planned or completed on schedule, if at all, and failure can occur at any time during the preclinical study or clinical trial process. Despite promising preclinical or clinical results, any product candidate can unexpectedly fail at any stage of preclinical or clinical development. The historical failure rate for product candidates in our industry is high. The results from preclinical studies or early clinical trials of a product candidate may not predict the results of later clinical trials of the product candidate, and interim results of a clinical trial are not necessarily indicative of final results. Furthermore, product candidates in later stages of clinical trials may fail to show the desired safety and efficacy characteristics despite having progressed through preclinical studies and initial clinical trials.

In particular, while we have results from the SAD and MAD portions of a Phase 1 clinical trial of LP352, we do not know how LP352 will perform in future clinical trials, including the ongoing PACIFIC Study. It is not uncommon to observe results in clinical trials that are unexpected based on preclinical studies and early clinical trials, and many product candidates fail in clinical trials despite very promising early results. Moreover, preclinical and clinical data may be susceptible to varying interpretations and analyses. A number of companies in the biopharmaceutical industry have suffered significant setbacks in clinical development even after achieving promising results in earlier studies, or after others, including regulatory authorities, disagreed with such companies' views and interpretations of the data and results from earlier preclinical studies or clinical trials. As we investigate LP352 for DEEs and other epileptic diseases, we may encounter difficulties that we have not yet encountered. For example, LP352 is being designed and dose-optimized for DEEs. This work is ongoing and we may encounter unforeseen difficulties. Furthermore, LP659 and other of our current or future product candidates may not be able to progress from preclinical to Phase 1 clinical development.

Clinical trials may not be conducted as planned or completed on schedule, if at all. A failure of a clinical trial can occur at any stage of testing. Events that may prevent successful or timely completion of clinical development include:

- delays in reaching a consensus with regulatory authorities on trial design or implementation;
- delays in obtaining regulatory authorization to commence a trial;
- the FDA's, EMA's or comparable regulatory authorities' failure to accept our proposed manufacturing processes and suppliers and/or requirement to provide additional information regarding our manufacturing processes before providing marketing authorization;
- delays in reaching agreement on acceptable terms with prospective clinical research organizations (CROs) and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- delays in obtaining approval from one or more institutional review boards (IRBs), or IRBs refusing to approve, suspending or terminating the trial at an investigational site, precluding enrollment of additional participants, or withdrawing their approval of the trial;
- delays in recruiting suitable patients to participate in our ongoing and planned clinical trials;
- changes to the clinical trial protocol;
- clinical sites deviating from trial protocol or dropping out of a trial;
- delays in manufacturing sufficient quantities of our product candidates or obtaining sufficient quantities of combination therapies for use in clinical trials;

- delays in having patients complete participation in a trial or return for post-treatment follow-up;
- participants choosing an alternative treatment for the indication for which we are developing our product candidates, or participating in competing clinical trials;
- lack of adequate funding to continue a trial;
- occurrence of adverse events (AEs) or serious adverse events (SAEs) associated with the product candidate that are viewed to outweigh its potential benefits;
- occurrence of SAEs in trials of the same class of agents conducted by other companies;
- selection of clinical end points that require prolonged periods of clinical observation or analysis of the resulting data;
- a facility manufacturing our product candidates or any of their components being ordered by the FDA or comparable foreign regulatory authorities to temporarily or permanently shut down due to violations of current good manufacturing practice (cGMP) regulations or other applicable requirements, or infections or cross-contaminations of product candidates in the manufacturing process;
- third-party clinical investigators losing the licenses or permits necessary to perform our clinical trials, not performing our clinical trials on our anticipated schedule or consistent with the clinical trial protocol (GCP) or other regulatory requirements;
- the impact of geopolitical and macroeconomic developments, including the COVID-19 pandemic or the ongoing conflict between Russia and Ukraine, on our ongoing and planned clinical trials; or
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols.

We could encounter delays if a clinical trial is suspended, terminated or modified by us, by the IRBs of the institutions in which such trials are being conducted, by a Data Safety Monitoring Board for such trial or by the FDA or comparable foreign regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or comparable foreign regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, changes in regulatory requirements and policies may occur, and we may need to amend clinical trial protocols to comply with these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical trial.

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

In addition, adverse geopolitical and macroeconomic developments, including disruptions caused by the COVID-19 or another pandemic or the ongoing conflict between Russia and Ukraine may increase the likelihood that we encounter difficulties or delays in initiating, screening, enrolling, conducting, or completing our ongoing and planned preclinical studies and clinical trials. Clinical site initiation and patient screening and enrollment may be delayed due to prioritization of hospital resources toward the COVID-19 or another pandemic, or to the extent the ongoing conflict between Russia and Ukraine escalates to involve additional countries, further economic sanctions or wider military conflict. Investigators and patients may not be able to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. Similarly, our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 or another virus, could be limited, which in turn could adversely impact our clinical trial operations. Additionally, we may experience interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel, quarantines or social distancing protocols imposed or recommended by federal or state governments, employers and others in connection with the COVID-19 or another pandemic. As a result of the COVID-19 pandemic, we have faced and may continue to face delays in meeting our anticipated timelines for our ongoing and planned clinical trials. For example, the initiation of the MAD portion of the Phase 1 clinical trial of LP352 was delayed, in part, as a result of the impact of the COVID-19 pandemic on the clinical site in the United Kingdom that conducted the SAD portion of the Phase 1 clinical trial for LP352, and subsequently we modified the protocol and relocated the MAD portion of such trial to a new clinical site in the United States. We announced topline data from the MAD portion of such trial in September 2021.

Any inability to successfully complete preclinical and clinical development could result in additional costs to us or impair our ability to generate revenue from future product sales and regulatory and commercialization milestones. In addition, if we make manufacturing or formulation changes to our product candidates, we may need to conduct additional testing to bridge our modified product candidate to earlier versions. Clinical trial delays could also shorten any periods during which we may have the exclusive

right to commercialize our product candidates, if approved, or allow our competitors to bring comparable products to market before we do, which could impair our ability to successfully commercialize our product candidates and may harm our business, financial condition, results of operations and prospects.

We have limited experience as a company in conducting clinical trials, have never conducted later-stage clinical trials or submitted an NDA or other marketing application, and may be unable to do so for any of our product candidates.

We are early in our development efforts for our product candidates, and we will need to successfully complete Phase 1 clinical trials and later-stage and pivotal clinical trials in order to obtain FDA or comparable foreign regulatory approval to market LP352, LP659, or any future product candidates. Carrying out clinical trials and the submission of marketing applications is complicated. To date, we have only conducted a limited number of Phase 1 trials for one of our product candidates, LP352.We have not completed any later stage or pivotal clinical trials, have limited experience as a company in preparing, submitting and prosecuting regulatory filings and have not previously submitted an NDA or other comparable foreign regulatory submission for any product candidate. We also plan to conduct a number of clinical trials for multiple product candidates in parallel over the next several years. This may be a difficult process to manage with our limited resources and may divert the attention of management. In addition, we have had limited interactions with the FDA and cannot be certain how many clinical trials of our product candidates will be required or how such trials will have to be designed. For example, we are currently conducting a "basket" Phase 1b/2a trial with LP352 in which participants with different DEEs are being enrolled and which is designed to include multiple clinically defined populations under one investigational protocol. We may seek to conduct our pivotal trials for LP352 with a basket design. A basket trial design could potentially decrease the time to study new populations by decreasing administrative burden, however, this trial may not provide opportunities for accelerated regulatory pathways and may not overcome limitations to extrapolating data from the experience in one disease to other diseases, because safety and efficacy results in each indication may be analyzed separately. Accordingly, clinical success in a basket trial, or any trial in one indication, may not predict success in another indication. The FDA and other regulatory health authorities may not view such a design or the data from such trials favorably. Consequently, we may be unable to successfully and efficiently execute and complete necessary clinical trials in a way that leads to regulatory submission and approval of any of our product candidates. We may require more time and incur greater costs than our competitors and may not succeed in obtaining regulatory approvals of product candidates that we develop. Failure to commence or complete, or delays in, our planned clinical trials, could prevent us from or delay us in submitting marketing applications for and commercializing our product candidates.

Because we have multiple product candidates in our pipeline and are considering a variety of target indications, we may expend our limited resources to pursue a particular product candidate 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 on specific product candidates, indications and development programs. We may also conduct several clinical trials for our product candidates in parallel over the next several years, which may make our decision as to which product candidates to focus on more difficult. For example, we are currently conducting the PACIFIC Study for LP352 for the treatment of seizures associated with DEEs, which may include Dravet syndrome, LGS and TSC, among others, which we initiated in the first quarter of 2022. Further, we are investigating preclinical studies of LP659 for multiple neurological diseases, and we have other compounds in earlier research. As a result, we may forgo or delay pursuit of opportunities with other product candidates or other indications that could have had greater commercial potential or likelihood of success. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. In addition, 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 future collaborations, licenses and other similar arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

Enrollment and retention of patients in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside our control.

Patient enrollment is a significant factor in the timing of clinical trials, and the timing of our clinical trials depends, in part, on the speed at which we can recruit patients to participate in our trials, as well as completion of required follow-up periods. We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials to such trial's conclusion as required by the FDA or other comparable foreign regulatory authorities. Additionally, certain clinical trials for future product candidates may be focused on indications with relatively small patient populations, which may further limit enrollment of eligible patients or may result in slower enrollment than we anticipate. The eligibility criteria of our clinical trials, once established, may further limit the pool of available trial participants. For example, the number of patients suffering from DEEs, such as Dravet syndrome, LGS and TSC, is small and, in some cases, has not been established with precision. If the actual number of patients with these diseases is smaller than we anticipate, we may encounter

difficulties in enrolling patients in our clinical trials, thereby delaying or preventing development and approval of our product candidates. Even once enrolled we may be unable to retain a sufficient number of patients to complete any of our trials.

Patient enrollment and retention in clinical trials depends on many factors, including the size and nature of the patient population, the severity of the disease under investigation, the nature of the trial protocol, the existing body of safety and efficacy data for the product candidate, the number and nature of competing treatments and ongoing clinical trials of competing therapies for the same indication, the proximity of patients to clinical sites, the eligibility criteria for the trial, the ability to adequately monitor patients during a trial, clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied, and the risk that patients will drop out of a trial before completing all site visits. There are limited patient pools from which to draw in order to complete our clinical trials in a timely and cost-effective manner, including due to the fact that the neurological diseases we target are rare.

Furthermore, our efforts to build relationships with patient communities may not succeed, which could result in delays in patient enrollment in our clinical trials, which could be exacerbated to the extent the ongoing conflict between Russia and Ukraine escalates to involve additional countries, further economic sanctions or wider military conflict. In addition, any negative results we may report in clinical trials of our product candidate may make it difficult or impossible to recruit and retain patients in other clinical trials of that same product candidate. Delays or failures in planned patient enrollment or retention may result in increased costs, program delays or both, which could have a harmful effect on our ability to develop our product candidates, or could render further development impossible. For example, the impact of public health epidemics, such as the COVID-19 pandemic, may delay or prevent patients from enrolling or from receiving treatment in accordance with the protocol and the required timelines, which could delay our clinical trials, or prevent us or our partners from completing our clinical trials at all, and harm our ability to obtain approval for such product candidate. Further, if patients drop out of our clinical trials, miss scheduled doses or follow-up visits, or otherwise fail to follow clinical trial protocols, whether as a result of the COVID-19 pandemic and related illness or actions taken to slow the spread of COVID-19 or otherwise, the integrity of data from our clinical trials may be compromised or not accepted by the FDA or other regulatory authorities, which would represent a significant setback for the applicable program. In addition, we may rely on CROs and clinical trial sites to ensure proper and timely conduct of our future clinical trials and, while we intend to enter into agreements governing their services, we will be limited in our ability to compel their actual performance.

Preliminary, topline and interim data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose preliminary or topline data from our clinical trials, such as our announcement in December 2022 of positive topline data from our Phase 1 clinical study evaluating PK and PD of LP352 in healthy volunteers, which are based on a preliminary analysis 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 study or 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 topline results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline 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, topline data should be viewed with caution until the final data are available. From time to time, we may also disclose interim data from our clinical studies. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. 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 the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product, product candidate or our business. If the topline 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, operating results, prospects or financial condition.

Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial potential or result in significant negative consequences following any potential marketing approval.

During the conduct of clinical trials, patients report changes in their health, including illnesses, injuries and discomforts, to their doctor. Often, it is not possible to determine whether or not the product candidate being studied caused these conditions. Regulatory authorities may draw different conclusions or require additional testing to confirm these determinations, if they occur.

In addition, it is possible that as we test our product candidates in larger, longer and more extensive clinical programs, or as use of these product candidates becomes more widespread if they receive regulatory approval, illnesses, injuries, discomforts and other AEs that were observed in earlier trials, as well as conditions that did not occur or went undetected in previous trials, will be reported by participants. Many times, side effects are only detectable after investigational product candidates are tested in large-scale, Phase 3 trials or, in some cases, after they are made available to patients on a commercial scale after approval. Patients in our ongoing or planned clinical trials may experience similar or other side effects after treatment with one or more of our product candidates. If additional clinical experience indicates that any of our current product candidates and any future product candidates has serious or life-threatening side effects or other side effects that outweigh the potential therapeutic benefit, the development of the product candidate may fail or be delayed, or, if the product candidate has received regulatory approval, such approval may be revoked, which would harm our business, prospects, operating results and financial condition.

Moreover, if we elect, or are required, to delay, suspend or terminate any clinical trial of our product candidates, the commercial prospects of our product candidates may be harmed and our ability to generate revenue through their sale may be delayed or eliminated. Any of these occurrences may harm our business, financial condition and prospects significantly.

LP352, our most advanced product candidate, is an oral, centrally acting, 5-HT2C receptor superagonist with no observed impact on 5-HT2B and 5-HT2A receptor subtypes in our preclinical studies to date. 5-HT2B and 5-HT2A receptor subtypes have been known to be associated with significant adverse side effects, including valvular heart disease and pulmonary arterial hypertension in the case of the 5-HT2B receptor, and hallucinations and mild to severe anxiety in the case of the 5-HT2A receptor. LP352 has the potential to be a clinically differentiated 5-HT2C superagonist for patients with DEEs. For example, fenfluramine, marketed as FINTEPLA, a non-specific 5-HT2 agonist, was approved for the treatment of seizures associated with Dravet syndrome and LGS by the FDA in 2020 and 2022, respectively. Fenfluramine has been associated with significant side effects and FINTEPLA has a Risk Evaluation and Mitigation Strategy (REMS) program requirement and a boxed warning. Another 5-HT2C agonist, lorcaserin, is also under evaluation for its potential to reduce seizures in patients with Dravet syndrome and refractory epilepsies. Lorcaserin was discovered by Arena and approved by the FDA for chronic weight management, marketed as BELVIQ by Eisai Inc. Lorcaserin was withdrawn from the market at the request of the FDA following the FDA's analysis of the CAMELLIA-TIMI 61 clinical trial, for which patients in the lorcaserin group demonstrated a numerically higher but not a statistically significantly higher rate of total cancer diagnoses (7.7% vs 7.1% placebo). Based on the results of this clinical trial, the FDA concluded that the risks of lorcaserin outweigh the benefits, and requested that lorcaserin be withdrawn from the market for the approved indication of weight management. However, the FDA authorized an expanded access program for patients with Dravet syndrome to continue to receive lorcaserin. LP352 was designed and developed by Arena to be the next generation to lorcaserin, with the goal of being a safer and more effective 5-HT2C agonist. We believe LP352's potential for high selectivity and novel chemistry gives it the potential to reduce seizures in DEE patients and overcome the known or perceived safety limitations of available drugs in the 5-HT2 class. However, we may not be correct, and the selectivity, specificity or other attributes of LP352 may result in similar or less desirable clinical profiles than less selective and specific available drugs or other product candidates. Further, in nonclinical toxicity studies of LP352 in rats and non-human primates (NHPs) conducted by Outpost Medicine, LLC prior to returning the product to Arena, certain male rats and NHPs of varying degrees of maturity in the respective high dose groups experienced minimal to slight degeneration/atrophy of the seminiferous tubules with reduced spermatocyte maturation. Although exposure levels for these high dose groups were estimated to be far in excess of planned human exposures in our clinical trials and no similar AEs were observed in our subsequent toxicity studies in sexually mature rats and NHPs, we may see similar findings in the future.

In addition, if any of our product candidates receive marketing approval, the FDA could require us to include a black box or other warning, or contraindication, in our product labeling, or adopt REMS to ensure that the benefits outweigh its risks, which may include, among other things, a medication guide outlining the risks of the drug for distribution to patients and a communication plan to health care practitioners. Furthermore, if we or others later identify undesirable side effects caused by our product candidates or other products with the same or related active ingredients, several other potentially significant negative consequences could result, including:

- regulatory authorities may suspend or withdraw approvals of such product, if approved;
- regulatory authorities may require additional warnings on the label or issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product;
- we may be required to change the way a product candidate is administered, conduct additional clinical trials or modify such product in some other way;
- regulatory authorities may require us to modify, suspend or terminate our clinical trials, conduct additional clinical trials or engage in costly post-marketing testing and surveillance to monitor the safety or efficacy of such product;

- we could be sued and held liable for harm caused to patients;
- undesirable side effects may limit physicians' or patients' willingness to initiate or continue therapy with such product;
- sales may decrease significantly;
- we may need to conduct a recall; and
- our brand and reputation or the reputation of any then-approved product may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of our product candidates and could significantly harm our business, prospects, financial condition and results of operations.

If the market opportunities for our product candidates are smaller than we estimate, even assuming approval of a product candidate, our business may suffer. Because the patient populations in the market for our product candidates may be small, we must be able to successfully identify patients and acquire a significant market share to achieve profitability and growth.

If the size of the market opportunities in each of our target indications is smaller than we anticipate, we may not be able to achieve profitability and growth. We focus on developing novel medicines for neurological diseases. Given the small number of patients who have the diseases that we are targeting, our eligible patient population and pricing estimates may differ significantly from the actual market addressable by our product candidates. 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 estimates that have been derived from a variety of sources, including scientific literature, patient foundations, or market research, and which may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these diseases. The number of patients may turn out to be lower than expected. Likewise, the potentially addressable patient population for each of our product candidates may be limited or may not be amenable to treatment with our product candidates, and new patients may become increasingly difficult to identify or gain access to, which would adversely affect our results of operations and our business.

We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than us.

The development and commercialization of pharmaceutical products is highly competitive. We face competition with respect to our current product candidates and will face competition with respect to any other product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. There are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of product candidates for the treatment of the indications that we are pursuing. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

DEEs are commonly treated with multiple combinations of anti-epileptic drugs (AEDs) though physician preference for administered therapies differs across different epilepsy types. Pharmaceutical companies, such as Lundbeck, Pfizer, and UCB have approved AEDs for the treatment of epilepsies. There are also non-pharmaceutical therapies for epilepsy patients, such as a ketogenic diet, vagus nerve stimulation, and surgery for some patients. Several companies have obtained FDA approval for the treatment seizures associated with DEEs. For example, ZTALMY (ganaxalone) was approved for the treatment of seizures associated with CDKL5 deficiency disorder in March 2022. Fenfluramine was approved for the treatment of seizures associated with Dravet syndrome in June 2020 and LGS in March 2022, and is available for patients through a REMS program. Epidiolex (cannabidiol) was approved for the treatment of seizures associated with Dravet syndrome and LGS in 2018, and the treatment of seizures associated with TSC in 2020, and DIACOMIT (stiripentol) was approved for seizures associated with Dravet syndrome in 2018. In addition, other companies are developing therapeutics for the treatment of DEEs, including alternative approaches such as gene therapy.

In the S1P receptor modulator space, there are four drugs that have been approved by the FDA for the treatment of certain indications in multiple sclerosis: fingolimod, ozanimod, ponesimod and siponimod. There are multiple additional S1P receptor modulators in development for additional therapeutic indications beyond multiple sclerosis, including in other neurological diseases. There are also numerous other drugs and product candidates in development for indications for which we might develop our product candidates.

There are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of product candidates for the treatment of the indications that we are pursuing. More established companies may have a competitive advantage over us due to their substantially greater size, financial, technical and other resources, and institutional experience. In particular, these companies have greater experience and expertise in securing reimbursement, government contracts,

relationships with key opinion leaders, conducting testing and clinical trials, obtaining and maintaining regulatory approvals and distribution relationships to market products, and marketing approved drugs. These companies also have significantly larger research and development staff and experienced marketing and manufacturing organizations and well-established sales forces. If we are not able to compete effectively against existing and potential competitors, our business and financial condition may be harmed.

The key competitive factors affecting the success of our product candidates are likely to be their efficacy and safety, the scope and limitations of marketing approval, success of regulatory approval, successful protection of our intellectual property, and the availability of funding and reimbursement.

As a result of these factors, our competitors may obtain regulatory approval of their drugs before we are able to, which may limit our ability to develop or commercialize our product candidates. Our competitors may also develop therapies that are safer, more effective, more widely accepted and cheaper than ours, and may also be more successful than us in manufacturing and marketing their drugs. These appreciable advantages could render our product candidates obsolete or non-competitive before we can recover the expenses of such product candidates' development and commercialization.

Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific, management and commercial personnel, establishing clinical trial sites and subject registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries.

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate and it is possible that any product candidates we may seek to develop in the future will never obtain regulatory approval. Neither we nor any future collaborator is permitted to market any of our product candidates in the United States until we receive regulatory approval of an NDA from the FDA.

Prior to obtaining approval to commercialize a product candidate in the United States or abroad, we or our collaborators must demonstrate with substantial evidence from adequate and well-controlled clinical trials, and to the satisfaction of the FDA or foreign regulatory agencies, that such product candidates are safe and effective for their intended uses. To demonstrate the safety of our clinical products, we may also be required to conduct extensive clinical trials and nonclinical studies, some of which have not been initiated or completed, and may not be completed for several years. For example, we believe that we will need to conduct additional nonclinical studies in juvenile animals, as well as develop a liquid formulation, to support the evaluation of LP352 in pediatric populations. We also expect that we will need to conduct additional toxicology, long-term carcinogenicity and other nonclinical studies to support the safety evaluation of LP352 and any of our product candidates intended to be administered for an extended period of time. There is no assurance our development or these studies will be successful. In addition, results from nonclinical studies and clinical trials can be interpreted in different ways. Even if we believe the nonclinical or clinical data for our product candidates are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. The FDA may also require us to conduct additional preclinical studies or clinical trials for our product candidates either prior to or post-approval, or it may object to elements of our clinical development program.

The FDA or any foreign regulatory bodies can delay, limit or deny approval of our product candidates or require us to conduct additional nonclinical or clinical testing or abandon a program for, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our preclinical studies or clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for any of its proposed indications;
- the population studied in the clinical trial may not be sufficiently broad or representative to assure safety in the full population for which we seek approval;

- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- serious and unexpected drug-related side effects experienced by participants in our clinical trials or by individuals using drugs similar to our product candidates;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its 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 acceptable or sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States or elsewhere, and we may be required to conduct additional clinical studies;
- the FDA's or the applicable foreign regulatory authority may disagree regarding the formulation, labeling and/or the specifications of our product candidates;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our data insufficient for approval.

Any of the above events could prevent us from achieving market approval of our product candidates and could substantially increase the costs of commercializing our product candidates. The demand for our product candidates could also be negatively impacted by any adverse effects of a competitor's product or treatment.

Of the large number of products in development, only a small percentage successfully complete the FDA or foreign regulatory approval processes and are commercialized. The lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market our product candidates, which would significantly harm our business, financial condition, results of operations and prospects.

Even if our current or future product candidates receive marketing approval, they may fail to achieve market acceptance by physicians, patients, third-party payors or others in the medical community necessary for commercial success.

Even if our current or future product candidates receive marketing approval, they may fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. If they do not achieve an adequate level of acceptance, we may not generate significant product revenue and may not become profitable. The degree of market acceptance of our current or future product candidates, if approved for commercial sale, will depend on a number of factors, including but not limited to:

- patient demand;
- the clinical indications for which the product candidate is approved;
- the efficacy and potential advantages compared to alternative treatments and therapies;
- the timing of market introduction of the product as well as competitive products;
- effectiveness of our sales, marketing and distribution efforts and those of the third parties with whom we may contract;
- the strength of our relationships with patient communities;
- the cost of treatment in relation to alternative treatments and therapies, including any similar generic treatments;
- our ability to offer such product for sale at competitive prices;
- the convenience and ease of administration compared to alternative treatments and therapies;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support;
- the availability of third-party coverage and adequate reimbursement;
- the willingness of patients to pay out-of-pocket in the absence of coverage and adequate reimbursement by third-party payors and government authorities;
- potential product liability claims;

- relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies, and patient satisfaction with the overall treatment experience;
- the prevalence and severity of any side effects from the use or potential misuse of any then-approved product; and
- any restrictions on the use of the product together with other medications.

Our efforts to educate physicians, patients, third-party payors and others in the medical community on the benefits of our product candidates may require significant resources and may never be successful. Such efforts may require more resources than are typically required due to the complexity and uniqueness of our product candidates.

In addition, if approved, LP352 may face challenges in gaining market acceptance by physicians, patients, third-party payors or others in the medical community as a result of it being a 5-HT2C agonist, which is part of an agonist class associated with significant risks and side effects. For example, fenfluramine, marketed as FINTEPLA, is a non-specific 5-HT2 agonist, has been associated with significant side effects and FINTEPLA has a REMS program requirement and a boxed warning. Another 5-HT2C agonist, lorcaserin, is also under evaluation for its potential to reduce seizures in patients with Dravet syndrome and refractory epilepsies. Lorcaserin was discovered by Arena and approved by the FDA for chronic weight management, marketed as BELVIQ by Eisai Inc. and withdrawn from the market at the request of the FDA based on a change in the FDA's risk-benefit assessment for the approved indication. However, the FDA authorized an expanded access program for patients with Dravet syndrome to continue to receive lorcaserin.

Although we aim to improve upon current 5-HT2C agonist product profiles with LP352, which was designed to be the next generation to lorcaserin, with the goal of being a safer and more effective 5-HT2C agonist, and which we believe has the potential to overcome the limitations of the currently available 5-HT2 class, if we are unable to do so and to educate physicians, patients, third-party payors and others in the medical community about this product candidate and successfully distinguish the safety profile of this product candidate to those of other products in the 5-HT2C agonist class, we may fail to gain market acceptance of LP352.

Because we expect sales of our product candidates, if approved, to generate substantially all of our revenues for the foreseeable future, the failure of our product candidates, if approved, to find market acceptance would harm our business and could require us to seek additional financing.

Even if we obtain regulatory approval for our current or future product candidates, they will remain subject to ongoing regulatory oversight.

Even if we obtain any regulatory approval for our current or any future product candidates, such approvals will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, import, export, sampling, record-keeping and submission of safety and other post-market information. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as on-going compliance with cGMPs and GCPs for any clinical trials that we may conduct post-approval. Any regulatory approvals that we receive for our current or future product candidates may also be subject to a REMS, limitations on the approved indicated uses for which the drug may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 trials, and surveillance to monitor the quality, safety and efficacy of the drug.

In addition, drug manufacturers and their facilities are subject to payment of user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP requirements and adherence to commitments made in the NDA or foreign marketing application. If we, or a regulatory authority, discover previously unknown problems with a drug, such as AEs of unanticipated severity or frequency, or problems with the facility where the drug is manufactured or if a regulatory authority disagrees with the promotion, marketing or labeling of that drug, a regulatory authority may impose restrictions relative to that drug, the manufacturing facility or us, including requesting a recall or requiring withdrawal of the drug from the market or suspension of manufacturing.

If we fail to comply with applicable regulatory requirements following approval of our current or future product candidates, a regulatory authority may:

- issue an untitled letter or warning letter asserting that we are in violation of the law;
- seek an injunction or impose administrative, civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve a pending NDA or NDA supplement, or comparable foreign marketing application (or any supplements thereto) submitted by us or our strategic partners;

- restrict or suspend the marketing or manufacturing of the drug;
- seize or detain the drug or otherwise require the withdrawal of the drug from the market;
- refuse to permit the import or export of product candidates; or
- refuse to allow us to enter into supply contracts, including government contracts.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize our current or future product candidates and harm our business, financial condition, results of operations and prospects.

In addition, the FDA's policies, and those of equivalent foreign regulatory agencies, may change and additional government regulations may be enacted that could cause changes to or delays in the drug review process, or suspend or restrict regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would harm our business, financial condition, results of operations and prospects.

We currently have no marketing and sales organization and have no experience as a company in commercializing products, and we may have to invest significant resources to develop these capabilities. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our products, we may not be able to generate product revenue.

We have not as a company commercialized a product and have limited or no internal sales, marketing or distribution capabilities. If any of our product candidates ultimately receives regulatory approval, we must build a marketing and sales organization with technical expertise and supporting distribution capabilities to commercialize each such product in the markets that we target, which will be expensive and time consuming, or collaborate with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. We currently plan to independently commercialize our product candidates in the United States by establishing a focused sales force and marketing infrastructure. We may opportunistically seek additional strategic collaborations to maximize the commercial opportunities for our product candidates outside of the United States. There are significant risks involved in building and managing a sales organization, including our ability to hire, retain and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products. We may not be able to enter into collaborations or hire consultants or external service providers to assist us in sales, marketing and distribution functions on acceptable financial terms, or at all. In addition, our product revenues and our profitability, if any, may be lower if we rely on third parties for these functions than if we were to market, sell and distribute any products that we develop ourselves. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we are not successful in commercializing our products, either on our own or through arrangements with one or more third parties, we may not be able to generate any future product revenue and we would incur significant additional losses.

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

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction. For example, even if the FDA grants regulatory approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion and reimbursement of the product candidate in those countries. However, a failure or delay in obtaining regulatory approval in one jurisdiction may negatively impact the regulatory approval process in others. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

Obtaining foreign regulatory approvals and establishing and maintaining compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we or any future collaborator fail to comply with the regulatory requirements in international markets or fail to 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.

Product liability lawsuits against us could cause us to incur substantial liabilities and could limit commercialization of any product candidate that we may develop.

We face an inherent risk of product liability exposure related to the testing of our current and any future product candidates in clinical trials and may face an even greater risk if we commercialize any product candidate that we may develop. Any side effects, manufacturing defects, failure to follow instructions, misuse or abuse associated with our product candidates could result in injury to a patient or even death. If we cannot successfully defend ourselves against claims that any such product candidates caused injuries, we could incur substantial liabilities and could incur reputational harm. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidate that we may develop;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- substantial monetary awards to trial participants or patients that may not be covered by insurance;
- significant time and costs to defend the related litigation;
- a diversion of management's time and our resources;
- withdrawal of clinical trial participants and termination of clinical trial sites or entire trial programs;
- initiation of investigations by regulators;
- the inability to commercialize any product candidate that we may develop;
- injury to our reputation and significant negative media attention; and
- a decline in our share price.

Large judgments have been awarded in class action and individual lawsuits based on drugs that had anticipated or unanticipated side effects. Any product liability insurance coverage that we obtain and maintain may not be adequate to cover all liabilities that we may incur. We anticipate that we will need to increase our insurance coverage each time we commence a clinical trial and if we successfully commercialize any product candidate. Insurance coverage is increasingly expensive. We may not be able to obtain or maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

Our product candidates may be regulated as controlled substances, the making, use, sale, importation, exportation, and distribution of which are subject to significant regulation by the U.S. Drug Enforcement Administration (DEA) and other regulatory agencies.

Our product candidates may be classified as controlled substances, which are subject to state, federal, and foreign laws and regulations regarding their manufacture, use, sale, importation, exportation, and distribution. Among other things, controlled substances are regulated under the federal Controlled Substances Act of 1970, and regulations of the DEA.

The DEA regulates controlled substances as Schedule I, II, III, IV or V substances. Schedule I substances by definition have no established medicinal use and may not be marketed or sold in the United States. A pharmaceutical product may be listed as Schedule II, III, IV or V, with Schedule II substances considered to present the highest risk of abuse and Schedule V substances the lowest relative risk of abuse among such substances. Prior to commercialization, centrally acting drugs are generally subject to review and potential scheduling by the DEA. It is possible that LP352 or our other product candidates may be regulated by the DEA as a Schedule IV controlled substance, which would subject such product candidates to additional restrictions regarding their manufacture, shipment, storage, sale and use, depending on the scheduling of the active ingredients, and may limit the commercial potential of any of our product candidates, if approved. For example, BELVIQ and FINTEPLA are Schedule IV controlled substances.

Various states also independently regulate controlled substances. Though state-controlled substances laws often mirror federal law, because the states are separate jurisdictions, they may separately schedule drugs as well. While some states automatically schedule a drug when the DEA does so, in other states there must be rulemaking or a legislative action. State scheduling may delay commercial sale of any controlled substance drug product for which we obtain federal regulatory approval and adverse scheduling could impair the commercial attractiveness of such product. We or our collaborators must also obtain separate state registrations in order to be able to obtain, handle and distribute controlled substances for clinical trials or commercial sale, and failure to meet

applicable regulatory requirements could lead to enforcement and sanctions from the states in addition to those from the DEA or otherwise arising under federal law.

For any of our product candidates classified as controlled substances, we and our suppliers, manufacturers, contractors, customers and distributors are required to obtain and maintain applicable registrations from state, federal and foreign law enforcement and regulatory agencies and comply with state, federal and foreign laws and regulations regarding the manufacture, use, sale, importation, exportation and distribution of controlled substances. There is a risk that DEA regulations may limit the supply of the compounds used in clinical trials for our product candidates, and, in the future, the ability to produce and distribute our products in the volume needed to meet commercial demand. Regulations associated with controlled substances govern manufacturing, labeling, packaging, testing, dispensing, production and procurement quotas, recordkeeping, reporting, handling, shipment and disposal. These regulations increase the personnel needs and the expense associated with development and commercialization of product candidates including controlled substances. The DEA, and some states, conduct periodic inspections of registered establishments that handle controlled substances. Failure to obtain and maintain required registrations or comply with any applicable regulations could delay or preclude us from developing and commercializing our product candidates containing controlled substances and subject us to enforcement action. The DEA may seek civil penalties, refuse to renew necessary registrations or initiate proceedings to revoke those registrations. In some circumstances, violations could lead to criminal proceedings. Because of their restrictive nature, these regulations could limit commercialization of any of our product candidates that are classified as controlled substances.

Risks Related to Regulatory Compliance

Our relationships with customers, healthcare providers, and third-party payors may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, other healthcare laws and regulations and data privacy and security laws and regulations, contractual obligations and self-regulatory schemes. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

Healthcare providers, including physicians, and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, principal investigators, consultants, customers and third-party payors may subject us to various federal and state fraud and abuse laws and other healthcare laws, including, without limitation, the federal Anti-Kickback Statute, the federal civil and criminal false claims laws and the law commonly referred to as the Physician Payments Sunshine Act and regulations. These laws will impact, among other things, our clinical research, as well as our proposed sales, marketing and educational programs. In addition, we may be subject to data privacy and security laws by both the federal government and the states in which we conduct or may conduct our business. The laws that will affect our operations include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from 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, in return for the purchase, recommendation, leasing or furnishing of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs. This statute has been interpreted to apply to, among other things, arrangements between pharmaceutical manufacturers on the one hand, and prescribers, purchasers and formulary managers on the other. A person or entity does not need to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation;
- federal civil and criminal false claims laws, including, without limitation, the False Claims Act, and civil monetary penalty laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid or other government payors that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. 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 federal False Claims Act;
- HIPAA, which created additional federal criminal statutes that prohibit, among other things, a person from knowingly and willfully executing a scheme or making false or fraudulent statements to defraud any healthcare benefit program, regardless of the payor (e.g., public or private). Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the HITECH and their implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization by entities subject to the rule, such as health plans, healthcare clearinghouses and certain healthcare providers, known as covered entities, and their respective business associates, individuals or entities that perform certain services on behalf of a covered entity that involves the use or disclosure of individually identifiable health information and their subcontractors that use, disclose or otherwise process individually identifiable health information;

- The Physician Payments Sunshine Act, 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 specific exceptions, to report annually to the Centers for Medicare & Medicaid Services (CMS), information related to: (i) payments or other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors), physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, anesthesiologist assistants and certified nurse midwives, and teaching hospitals during the previous year; and (ii) ownership and investment interests held by physicians and their immediate family members;
- state and foreign law equivalents of each of the above federal laws, state laws that require manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and/or information regarding drug pricing, state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or to adopt compliance programs as prescribed by state laws and regulations, or that otherwise restrict payments that may be made to healthcare providers, state laws and regulations that require drug manufacturers to file reports relating to drug pricing and marketing information, and state and local laws that require the registration of pharmaceutical sales representatives; and
- state and foreign laws that govern the privacy and security of personal information, including health-related 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. By way of example, California enacted the California Consumer Privacy Act (CCPA), effective January 1, 2020, which gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. Moreover, a new privacy law, the California Privacy Rights Act (CPRA) operative January 1, 2023, is anticipated to expand the CCPA's obligations on businesses. The CCPA and CPRA may increase our compliance costs and potential liability. Further, the EU General Data Protection Regulation (GDPR) imposes obligations and restrictions on the collection and use of personal data relating to individuals in the European Economic Area (EEA) (including health data). The GDPR increases obligations with respect to clinical trials conducted in the EEA by expanding the definition of personal data and requiring changes to informed consent practices and more detailed notices for clinical trial participants and investigators.

In Europe, the GDPR, as well as EU and EEA Member State implementing legislations, apply to the collection and processing of personal data, including health-related information. Importantly, the GDPR materially expands the definition of what is expressly provided to constitute "personal data" including by clarifying that the GDPR applies to pseudonymized (i.e. key-coded) data, which is often processed by sponsors in the context of clinical trials. EU and EEA Member States are also able to legislate separately on health and genetic data, and we must comply with these local laws where we operate. Also, notwithstanding the UK's withdrawal from the EU, the data protection obligations of the GDPR continue to apply to UK-related processing of personal data under the so-called "UK GDPR". These GDPR regulations have "extra-territorial" reach in that it applies (inter-alia) to any processing of personal data that concerns the offering of goods or services to individuals in the EEA or UK (as applicable) and/or the monitoring of their behavior, regardless of the existence of an establishment in the EEA or UK (as applicable). As such, these GDPR regulations apply to any clinical trials and other operations taking in place in the EEA and UK. The GDPR provides for robust regulatory enforcement and substantial fines. While the GDPR affords some flexibility in determining how to comply with the various requirements, significant effort and expense has been, and will continue to be, invested to ensure continuing compliance. In Switzerland, the Federal Act on Data Protection (DPA), also applies to the collection and processing of personal data, including health-related information, by companies located in Switzerland, or in certain circumstances, by companies located outside of Switzerland. The applicability of the DPA will also result in an increase of costs of compliance, risks of noncompliance and penalties for noncompliance.

These data privacy and security laws impose strict obligations on the ability to process personal data, including health-related information, in particular in relation to their collection, use, disclosure and transfer. This includes several requirements relating to (i) obtaining, in some situations, the consent of the individuals to whom the personal data relates, (ii) the information provided to the individuals about how their personal data is used, (iii) ensuring the security and confidentiality of the personal data, (iv) the obligation to notify regulatory authorities and affected individuals of personal data breaches, (v) extensive internal privacy governance obligations, and (vi) obligations to honor rights of individuals in relation to their personal data (for example, the right to access, correct and delete their personal data).

In addition, the GDPR regulations prohibit the transfer of personal data from the EEA and the UK to the United States, and other countries in respect of which the European Commission or other relevant regulatory body has not issued a so-called "adequacy decision" (known as "third countries"). Switzerland has adopted similar restrictions under the DPA. The implementation of the processes, including agreements with all relevant CROs, sub-processors and other third parties, is complex and time-consuming. As such, transfers of personal data from the EEA, UK and/or Switzerland to the United States and other third countries may not fully comply with the cross-border data transfer restrictions set out in the applicable data privacy and security regulations. Additionally,

other countries outside of Europe have enacted or are considering enacting similar cross-border data transfer restrictions and laws requiring local data residency, which could increase the cost and complexity of operating our business.

Furthermore, following Brexit, the relationship between the UK and the EEA in relation to certain aspects of data protection law remains somewhat uncertain, and we may be required to implement processes and put agreements in place to enable transfers of personal data from the EEA to the UK, which could further increase the complexity and costs in our operations.

Compliance with U.S. and international data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. Actual or perceived failure to comply with these laws and regulations could result in government enforcement actions (which could include civil, criminal and administrative penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial participants, employees and other individuals about whom we or our potential collaborators obtain personal information, as well as the providers who share this information with us, may limit our ability to collect, use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws.

It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations 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 of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws and the curtailment or restructuring of our operations.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance and/or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements. The laws and regulations discussed in these risk factors are intended to be examples, and updates to these laws and regulations, as well as other laws and regulations, could have a material effect on our operations and prospects.

Coverage and adequate reimbursement may not be available for our current or any future product candidates, which could make it difficult for us to sell profitably, if approved.

Market acceptance and sales of any product candidates that we commercialize, if approved, will depend in part on the extent to which coverage and adequate reimbursement for these drugs and related treatments will be available from third-party payors, including government health administration authorities, managed care organizations and other private health insurers. Third-party payors decide which therapies they will pay for and establish reimbursement levels. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. However, decisions regarding the extent of coverage and amount of reimbursement to be provided for any product candidates that we develop will be made on a payor-by-payor basis. One third-party payor's determination to provide coverage for a drug does not assure that other payors will also provide coverage, and adequate reimbursement, for the drug. Additionally, a third-party payor's decision to provide coverage for a therapy does not imply that an adequate reimbursement rate will be approved. Each third-party payor determines whether or not it will provide coverage for a therapy, what amount it will pay the manufacturer for the therapy, and on what tier of its formulary it will be placed. The position on a third-party payor's list of covered drugs, or formulary, generally determines the co-payment that a patient will need to make to obtain the therapy and can strongly influence the adoption of such therapy by patients and physicians. Patients who are prescribed treatments for their conditions and providers prescribing such services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use our drugs unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our drugs.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Third-party payors are developing increasingly sophisticated methods of controlling healthcare costs by limiting coverage and the amount of reimbursement for particular medications, requiring drug companies to provide them with varying levels of discounts from list prices and/or challenging the value of list prices charged for medical products. Similarly, the containment of healthcare costs has become a priority for federal and state governments. Coverage and reimbursement may not be available for any drug that we commercialize and, if reimbursement

is available, the level of reimbursement is uncertain. Inadequate coverage and reimbursement may impact the demand for, or the price of, any drug for which we obtain marketing approval. If coverage and adequate reimbursement are not available, or are available only to limited levels, we may not be able to successfully commercialize our current and any future product candidates that we develop. Further, coverage policies and third-party payor reimbursement rates may change at any time. Therefore, even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Healthcare legislative reform measures may have a negative impact on our business and results of operations.

In the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities, and affect our ability to profitably sell any product candidates for which we obtain marketing approval.

Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

Reform measures that result in decreased physician reimbursement may adversely affect our business. Further, any reduction in reimbursement from Medicare or other governmental programs may result in a similar reduction in payments from private payors.

Also, there has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which have resulted in several U.S. presidential executive orders, Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. Additionally, based on a recent executive order, the Biden administration expressed its intent to pursue certain policy initiatives to reduce drug prices. On August 16, 2022, President Biden signed into law the Inflation Reduction Act of 2022 (IRA), which among other things extends enhanced subsidies for individuals purchasing health insurance coverage through plan year 2025 in the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the ACA), marketplaces. 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. In response to Biden's executive order, on September 9, 2021, the Department of Health and Human Services, or 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 to advance these principles. In addition, the IRA, among other things, (1) directs HHS to negotiate the price of certain single-source drugs and biologics covered under Medicare and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions will take effect progressively starting in fiscal year 2023, although they may be subject to legal challenges. The IRA is likely to have a significant impact on the pharmaceutical industry. 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.

We cannot predict what healthcare reform initiatives may be adopted in the future. We expect that these and other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved drug. 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 drugs.

If any of our current or future product candidates are approved for marketing, and we are found to have improperly promoted off-label uses, or if physicians prescribe or use any of our current or future product candidates off-label, we may become subject to prohibitions on the sale or marketing of any of our current or future product candidates, significant fines, penalties, sanctions, or product liability claims, and our image and reputation within the industry and marketplace could be harmed.

The FDA, Department of Justice (DOJ), and comparable foreign authorities strictly regulate the marketing and promotional claims that are made about pharmaceutical products, including our product candidates LP352 and LP659. In particular, a product may not be promoted for uses or indications that are not approved by the FDA or comparable foreign authorities as reflected in the product's approved labeling. Although physicians 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 for which marketing

clearance has not been issued. If we are found to have promoted such off-label uses, we may receive warning letters from the FDA and comparable foreign authorities and become subject to significant liability, which would materially harm our business. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. If we become the target of such an investigation or prosecution based on our marketing and promotional practices, we could face similar sanctions, which would materially harm our business. In addition, management's attention could be diverted from our business operations, significant legal expenses could be incurred, and our reputation could be damaged. The FDA and other governmental authorities have also required that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed in order to resolve enforcement actions. If we are deemed by the FDA, DOJ, or other governmental authorities to have engaged in the promotion of any current or future product candidates for off-label use, we could be subject to certain prohibitions or other restrictions on the sale or marketing of our products and operations, or significant fines and penalties, and the imposition of these sanctions could also affect our reputation and position within the industry.

We may not be able to obtain or maintain orphan drug designations or exclusivity for our product candidates, which could limit the potential profitability of our product candidates.

Regulatory authorities in some jurisdictions, including the United States, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act of 1983, the FDA may designate a drug as an orphan drug if it is a drug 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. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and application fee waivers. After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation, however, neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process. Generally, if a drug with an orphan drug designation subsequently receives the first marketing approval for an indication for which it receives the designation, then the drug is entitled to a period of marketing exclusivity that precludes the applicable regulatory authority from approving another marketing application for the same drug for the same indication for the exclusivity period except in limited situations. For purposes of small molecule drugs, the FDA defines "same drug" as a drug that contains the same active moiety and is intended for the same use as the drug in question. A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation.

We intend to pursue orphan drug designation for one or more of our product candidates, as well as for potential other future product candidates. Obtaining orphan drug designations is important to our business strategy; however, obtaining an orphan drug designation can be difficult and we may not be successful in doing so. Even if we were to obtain orphan drug designation for a product candidate, we may not obtain orphan exclusivity and that exclusivity may not effectively protect the drug from the competition of different drugs for the same condition, which could be approved during the exclusivity period. Additionally, after an orphan drug is approved, the FDA could subsequently approve another application for the same drug for the same indication if the FDA concludes that the later drug is shown to be safer, more effective or makes a major contribution to patient care. Orphan drug exclusive marketing rights in the United States also may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. The failure to obtain an orphan drug designation for any product candidates we may develop, the inability to maintain that designation for the duration of the applicable period, or the inability to obtain or maintain orphan drug exclusivity could reduce our ability to make sufficient sales of the applicable product candidate to balance our expenses incurred to develop it, which would have a negative impact on our operational results and financial condition.

Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the FDA have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, at times during the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

By way of another example, in response to the global COVID-19 pandemic, on March 10, 2020, the FDA announced its intention to postpone most foreign inspections of manufacturing facilities and products through April 2020, and subsequently, and on March 18, 2020, the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. On July 10, 2020, the FDA announced its intention to restart routine pre-announced surveillance inspections of domestic manufacturing facilities subject to a risk-based prioritization system. The FDA intends to use this risk-based assessment system to identify the categories of regulatory activity that can occur within a given geographic area, ranging from mission critical inspections to resumption of all regulatory activities. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Risks Related to Our Intellectual Property

We depend on intellectual property licensed from third parties, including Arena, and the failure by us or our licensors to protect the licensed intellectual property or the termination of our license could result in the loss of significant rights, which would harm our business.

We are dependent on technology, patents, know-how, and proprietary materials, both our own and licensed from Arena. We entered into the Arena License Agreement pursuant to which we acquired an exclusive, royalty bearing, sublicensable, worldwide license to develop and commercialize LP352 for any use in humans, LP659 for the treatment of certain CNS and peripheral nervous system indications, and certain other compounds for CNS indications. Any termination of this license will result in the loss of significant rights and will restrict our ability to develop and commercialize our product candidates. If we or Arena fails to adequately protect this intellectual property, or if we seek to expand the field of our license to include additional indications we determine are advantageous or necessary for us to develop a licensed compound and Arena does not consent, our ability to commercialize these compounds could suffer.

Agreements under which we license intellectual property or technology to or from third parties may 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 technology or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on 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. Our business also would suffer if any current or future licensors fail to abide by the terms of the license, if we or the licensors fail to enforce licensed patents against infringing third parties, if the licensed patents or other rights are found to be invalid or unenforceable, or if we are unable to enter into necessary licenses on acceptable terms. Moreover, our licensors may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to claims, regardless of their merit, that we are infringing or otherwise violating the licensor's rights.

Furthermore, while we cannot currently determine the amount of the royalty obligations we would be required to pay on sales of future products, if any, the amounts may be significant. The amount of our future royalty obligations will depend on the technology and intellectual property we use in products that we successfully develop and commercialize, if any. Therefore, even if we successfully develop and commercialize products, we may be unable to achieve or maintain profitability.

In addition, the growth of our business will likely depend in part on our ability to acquire or in-license additional proprietary rights, including to advance our research or allow commercialization of our product candidates. In that event, we may be required to expend considerable time and resources to develop or license replacement technology. For example, our programs may involve additional technologies or product candidates that may require the use of additional proprietary rights held by third parties. Furthermore, other pharmaceutical companies and academic institutions may also have filed or are planning to file patent applications potentially relevant to our business. Our product candidates may also require specific formulations or other technology to work effectively and efficiently. These formulations or technology may be covered by intellectual property rights held by others. From time to time, in order to avoid infringing these third-party patents, we may be required to license technology from additional third parties to further develop or commercialize our product candidates. We may be unable to acquire or in-license any relevant third-party intellectual property rights, including any such intellectual property rights required to manufacture, use or sell our product candidates, that we identify as necessary or important to our business operations. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all, and as a result we may be unable to develop or commercialize the affected product candidates, and we may have to abandon development of the relevant research programs or product candidates, which would harm our business. We may need to cease use of the compositions or methods covered by such third-party intellectual property rights, and may need to seek to develop alternative approaches that do not infringe on such intellectual property rights which may entail additional costs and

development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we are able to obtain a license under such intellectual property rights, any such license may be non-exclusive, which may allow our competitors' access to the same technologies licensed to us.

The licensing and acquisition of third-party intellectual property rights is a competitive practice, and companies that may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates. More established companies may have a competitive advantage over us due to their larger size and cash resources or greater clinical development and commercialization capabilities. There can be no assurance that we will be able to successfully complete such negotiations and ultimately acquire the rights to the intellectual property surrounding the additional product candidates that we may seek to acquire.

Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues and is complicated by the rapid pace of scientific discovery in our industry. Disputes may also arise between us and our licensors regarding intellectual property subject to a license agreement, including those relating to:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the license agreement;
- our right to sublicense patent and other rights to third parties under collaborative development relationships;
- whether we are complying with our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations;
- the priority of invention of patented technology;
- the amount and timing of payments owed under license agreements; and
- the allocation of ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and by us and our partners.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates. We are generally also subject to all of the same risks with respect to protection of intellectual property that we license as we are for intellectual property that we own, which are described below. If we or our licensors fail to adequately protect this intellectual property, our ability to commercialize our products could suffer.

Furthermore, our existing license agreements impose, and we expect that future license agreements will impose, various diligence, milestone payment, royalty and other obligations on us and if we fail to comply with our obligations under these agreements, including due to the impact of adverse macroeconomic and geopolitical developments such as the COVID-19 pandemic or the invasion of Ukraine by Russia, or any economic slowdowns, recessions, market corrections, inflation, rising interest rates and tightening of credit markets resulting therefrom, on our business operations or our use of the intellectual property licensed to us in an unauthorized manner, or we are subject to a bankruptcy, we may be required to pay damages and the licensor may have the right to terminate the license.

We depend, in part, on our licensors to file, prosecute, maintain, defend, or enforce patents and patent applications that are material to our business.

Patents relating to our product candidates may be controlled by our licensor. Licensors may have rights to file, prosecute, maintain, and defend the patents we have licensed from such licensor. Our ability to settle legal claims may require consent of licensors. If our licensor or any future licensees having rights to file, prosecute, maintain, and defend our patent rights fail to conduct these activities for patents or patent applications covering any of our product candidates, 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, or selling competing products. We cannot be certain that such activities by our licensor has been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents or other intellectual property rights. If our licensor has the right to control enforcement of our licensed patents or defense of any claims asserting the invalidity of these patents and, even if we are permitted to pursue such enforcement or defense, we cannot ensure the cooperation of our licensor. We cannot be certain that our licensor will allocate sufficient resources or prioritize its or our enforcement of such patents or defense of such claims to protect our interests in the licensed patents. Even if we are not a party to these legal actions, an adverse outcome could harm our business because it might prevent us from continuing to license intellectual property that we may need to operate our business. In addition, even when we have the right to control patent prosecution of licensed patents and patent applications, enforcement of licensed patents, or defense of claims asserting the invalidity of those patents, we may still be adversely affected or prejudiced by actions or inactions

of our licensor and its counsel that took place prior to or after our assuming control. In the event we breach any of our obligations related to such prosecution, we may incur significant liability to our licensing partners.

For most licensed products under the Arena License Agreement, including LP352 and LP659, we have the first right to control the prosecution and enforcement of the licensed patent applications and patents. However, we have an obligation to reasonably cooperate with Arena and will to some extent depend on Arena's cooperation with us to prosecute and enforce such intellectual property. A disagreement between us and Arena with respect to the prosecution or enforcement of the patent applications or patents, or unsuccessful actions to prosecute or enforce the patent applications or patents, could adversely affect our intellectual property rights.

We may enter into collaboration agreements and strategic alliances, and we may not realize the anticipated benefits of such collaborations or alliances. We may wish to form collaborations in the future with respect to our product candidates, but may not be able to do so or to realize the potential benefits of such transactions, which may cause us to alter or delay our development and commercialization plans.

We intend to broaden the global reach of our platform by potentially selectively collaborating with leading biopharmaceutical companies. We intend to retain significant economic and commercial rights to our programs in key geographic areas that are core to our long-term strategy. As a result, we intend to periodically explore a variety of possible additional strategic collaborations in an effort to gain access to additional product candidates or resources. At the current time, we cannot predict what form such a strategic collaboration might take. We are likely to face significant competition in seeking appropriate strategic collaborators, and strategic collaborations can be complicated and time consuming to negotiate and document. We may not be able to negotiate strategic collaborations on acceptable terms, or at all. We are unable to predict when, if ever, we will enter into any additional strategic collaborations because of the numerous risks and uncertainties associated with establishing them.

Research and development collaborations are subject to numerous risks, which may include the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to a collaboration, and may not commit sufficient efforts and resources, or may misapply those efforts and resources;
- collaborators may conduct their own clinical trials which may not be compliant, may not be successful or may generate contradictory results;
- collaborators may not pursue development and commercialization of collaboration 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 may delay, provide insufficient resources to, or modify or stop clinical trials for collaboration product candidates;
- collaborators could independently develop, or develop with third parties, or acquire products outside of the collaboration that compete directly or indirectly with our products or 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;
- a collaborator or series of collaborators may improperly or unknowingly sell product directly (or indirectly to a potential customer) into the "gray market" whereby our branded products are diverted from authorized sales channels into the hands of dealers, brokers or the open market, and may result in unauthorized sale of our product in a specific country or region;
- 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 cause the delay or termination of the research, development or commercialization of our product candidates, or that result 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 and personnel to pursue further development or commercialization of the applicable product candidates;
- a collaborator's sales and marketing activities or other operations may not be in compliance with applicable laws resulting in civil or criminal proceedings; and

- collaborators may own or co-own intellectual property covering our products that results from our collaborating with them, and in such cases, we may not have the exclusive right to commercialize such intellectual property.

The development and potential commercialization of our product candidates will require substantial additional capital to fund expenses. We may form or seek further strategic alliances, create joint ventures or collaborations, or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our product candidates and any future product candidates that we may develop, including in territories outside the United States or for certain indications. These transactions can entail numerous operational and financial risks, including exposure to unknown liabilities, disruption of our business and diversion of our management's time and attention in order to manage a collaboration or develop acquired products, product candidates or technologies, incurrence of substantial debt or dilutive issuances of equity securities to pay transaction consideration or costs, higher than expected collaboration, acquisition or integration costs, write-downs of assets or goodwill or impairment charges, increased amortization expenses, difficulty and cost in facilitating the collaboration or combining the operations and personnel of any acquired business, impairment of relationships with key suppliers, manufacturers or customers of any acquired business due to changes in management and ownership and the inability to retain key employees of any acquired business. As a result, if we enter into acquisition or in-license agreements or strategic partnerships, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction or such other benefits that led us to enter into the arrangement.

In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. We may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy. If and when we collaborate with a third-party for development and commercialization of a product candidate, we can expect to relinquish some or all of the control over the future success of that product candidate to the third-party. Our ability to reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of our technologies, product candidates and market opportunities. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. We may also be restricted under any license agreements from entering into agreements on certain terms or at all with potential collaborators.

As a result of these risks, we may not be able to realize the benefit of our existing collaborations or any future collaborations or licensing agreements we may enter into. In addition, there have been a significant number of recent business combinations among large pharmaceutical and biomedical companies that have resulted in a reduced number of potential future collaborators and changes to the strategies of the combined company. As a result, we may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of such product candidate, reduce or delay one or more of our other development programs, delay the potential commercialization or reduce the scope of any planned sales or marketing activities for such product candidate, or increase our expenditures and undertake development, manufacturing or commercialization activities at our own expense. If we elect to increase our expenditures to fund development, manufacturing or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

Additionally, we may sometimes collaborate with academic institutions to accelerate our preclinical research or development under written agreements with these institutions. Typically, these institutions provide companies like us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. Regardless of such option, we may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to other parties, potentially blocking our ability to pursue our program. If we are unable to successfully obtain rights to required third-party intellectual property or to maintain the existing intellectual property rights we have, we may have to abandon development of such program and our business and financial condition could suffer.

Our products will require specific constituents to work effectively and efficiently, and rights to those constituents are and, in the future, may be held by others. We may be unable to in-license any rights to constituents, methods of use, processes or other third-party intellectual property rights from third parties that we identify. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, which would harm our business. In that event, we may be required to expend significant time and resources to develop or license replacement technology. Any delays in entering into new collaborations or strategic partnership agreements related to our product candidates could delay the development and commercialization of our product candidates in certain geographies, which could harm our business prospects, financial condition, and results of operations.

We may be dependent on intellectual property licensed or sublicensed to us from, or for which development was funded or otherwise assisted by, government agencies or academic or other institutions, for development of our technology and product candidates. Failure to meet our own obligations to our licensors or upstream licensors, including such government agencies or academic or other institutions, may result in the loss of our rights to such intellectual property, which could harm our business.

Government agencies or academic or other institutions may provide funding, facilities, personnel or other assistance in connection with the development of the intellectual property rights owned by or licensed to us. Such government agencies may have retained rights in such intellectual property, including the right to grant or require us to grant mandatory licenses or sublicenses to such intellectual property to third parties under certain specified circumstances, including if it is necessary to meet health and safety needs that we are not reasonably satisfying or if it is necessary to meet requirements for public use specified by federal regulations, or to manufacture products in the United States. Any exercise of such rights, including with respect to any such required sublicense of these licenses could result in the loss of significant rights and could harm our ability to commercialize licensed products.

If we are unable to obtain and maintain patent protection for our current or any future product candidates, or if the scope of the patent protection obtained is not sufficiently broad, we may not be able to compete effectively in our markets.

We anticipate that we will file additional patent applications both in the United States and in other countries, as appropriate. However, we cannot predict:

- if and when any patents will issue;
- the degree and scope of protection any issued patents will afford us against competitors, including whether third parties will find ways to invalidate or otherwise circumvent our patents;
- whether others will apply for or 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 defend our patent rights, which may be costly whether we win or lose; or
- whether the patent applications that we own, or in-license will result in issued patents with claims that cover our product candidates or uses thereof in the United States or in foreign countries.

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our development programs and product candidates. Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our current and any future product candidates. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our current and future development programs and product candidates. The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner, including as a result of the COVID-19 pandemic impacting our, our licensors’ or governmental patent offices' operations.

It is possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our current or any future product candidates in the United States or in foreign countries. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found, which can invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfully issue and even if such patents cover our current or any future product candidates, third parties may challenge their scope, validity, or enforceability, which may result in such patents being narrowed, invalidated, or held unenforceable. Any successful opposition to these patents or any other patents owned by or licensed to us could deprive us of rights necessary for the successful commercialization of any product candidates or companion diagnostic that we may develop. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate or companion diagnostic under patent protection could be reduced.

If the patent applications we hold or have in-licensed with respect to our development programs and product candidates fail to issue, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for our current or any future product candidates, it could dissuade companies from collaborating with us to develop product candidates, and threaten our ability to commercialize, future drugs. Any such outcome could have a negative effect on our business.

Composition of matter patents for pharmaceutical products often provide a strong form of intellectual property protection for those types of products, as such patents provide protection without regard to any method of use. We cannot be certain, however, that the claims in our pending patent applications covering the composition of matter of our product candidates will be considered patentable by the U.S. Patent and Trademark Office (USPTO), or by patent offices in foreign countries, or that the claims in any of our issued patents will be considered valid and enforceable by courts in the United States or foreign countries. Method of use patents

protect the use of a product for the specified method. This type of patent does not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their product for our targeted indications, physicians may prescribe these products "off-label" for those uses that are covered by our method of use patents. 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 enforce against.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. 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 file for patent protection. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or drugs, in whole or in part, or which effectively prevent others from commercializing competitive technologies and drugs.

Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. These changes could also increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. On September 16, 2011, the Leahy-Smith America Invents Act (Leahy-Smith Act) was signed into law. The Leahy-Smith Act included several significant changes to U.S. patent law that impacted how patent rights could be prosecuted, enforced and defended. In particular, the Leahy-Smith Act also included provisions that switched the United States from a "first-to-invent" system to a "first-to-file" system, allowed third party submission of prior art to the USPTO during patent prosecution and set forth additional procedures to attack the validity of a patent by the USPTO-administered post-grant proceedings. Under a first-to-file system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to the patent on an invention regardless of whether another inventor had made the invention earlier. The USPTO developed new regulations and procedures governing the administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, became effective on March 16, 2013. It remains unclear what, if any, impact the Leahy-Smith Act will have on the operation of our business. 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 issued patents, all of which could have a negative effect on our business.

Moreover, we may be subject to a third-party pre-issuance submission of prior art to the USPTO or become involved in opposition, derivation, reexamination, inter partes review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or drugs and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize drugs without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. 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 drugs, or limit the duration of the patent protection of our technology and drugs. Moreover, patents have a limited lifespan. In the United States, if all maintenance fees are paid timely, the natural expiration of a patent is generally 20 years from the earliest filing date of a non-provisional patent application. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. For instance, a patent term extension based on regulatory delay may be available in the United States. However, only a single patent can be extended for each marketing approval, and any patent can be extended only once, for a single product. Moreover, the scope of protection during the period of the patent term extension does not necessarily extend to all claims, but instead only to claims that read on the product as approved. Laws governing analogous patent term extensions in foreign jurisdictions vary widely, as do laws governing the ability to obtain multiple patents from a single patent family. Additionally, we may not receive an extension if we fail to exercise due diligence during the testing phase or regulatory review process, apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. If we are unable to obtain patent term extension or restoration, or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our product will be shortened and our competitors may obtain approval of competing products following our patent expiration and may take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data to launch their product earlier than might otherwise be the case, and our revenue could be reduced, possibly materially. In addition, although upon issuance in the United States a patent's life can be increased based on certain delays caused by the USPTO, this increase can be reduced or eliminated based on certain delays caused by the patent applicant during patent prosecution. Without patent protection for our current or future product candidates, including once the patent life has expired even if patents covering our product

candidates are obtained, we may be open to competition from generic versions of such drugs. 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. Even if patents covering our product candidates are obtained, once the patent life has expired for a product, we may be open to competition from generic medications. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing drugs similar or identical to ours.

Even if we have or obtain patents covering our products or methods, we may still be barred from making, using and selling such products or methods because of the patent rights of others. Others may have filed, and in the future may file, patent applications covering compositions, products or methods that are similar or identical to ours, which could materially affect our ability to successfully develop our technology or to successfully commercialize any approved products alone or with collaborators.

Patent applications in the United States and elsewhere are generally 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. Therefore, patent applications covering our methods and products could have been filed by others without our knowledge. Additionally, pending claims in patent applications which have been published can, subject to certain limitations, be later amended in a manner that could cover our platform technologies or related products. These patent applications may have priority over patent applications filed by us.

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

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and/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 and licensed patents and/or applications and any patent rights we may own or license in the future. We rely on our outside counsel, patent annuity service providers, or our licensing partners to pay these fees due to non-U.S. patent agencies. The USPTO and various non-U.S. government patent agencies require compliance with several procedural, documentary, and other similar provisions during the patent application process. We will employ one or more reputable law firms and other professionals to help us comply and 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 non-compliance 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 harm our business.

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

Given the amount of time required for the development, testing and regulatory review of new product candidates such as LP352, patents protecting such candidates might expire before or shortly after such candidates are commercialized. We expect to seek extensions of patent terms in the United States and, if available, in other countries where we are prosecuting patents. In the United States, the Drug Price Competition and Patent Term Restoration Act of 1984 permits a patent term extension of up to five years beyond the normal expiration of the patent, which is limited to the approved indication (or any additional indications approved during the period of extension). However, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. If this occurs, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their drug earlier than might otherwise be the case.

Our intellectual property rights do not necessarily protect against all potential threats to our business.

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. These risks and uncertainties include the following:

- others may be able to make compounds or formulations that are similar to our product candidates but that are not covered by the claims of any patents, should they issue, that we own or control;
- we or any strategic partners might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own or control;
- we might not have been the first to file patent applications covering certain of the product candidates or inventions we own or control;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;

- pending patent applications that we own or control may not lead to issued patents;
- issued patents that we own or control may be held invalid or unenforceable as a result of legal challenges;
- our competitors might conduct research and development activities in the United States and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we do not have patent rights and then use the information learned from such activities to develop competitive drugs for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a negative impact on the success of our business.

Our commercial success depends, in part, upon our ability and the ability of our current or future collaborators to develop, manufacture, market and sell our current and any future product candidates and use our proprietary technologies without infringing the proprietary rights and intellectual property of third parties. The biotechnology and pharmaceutical industries are characterized by extensive and complex litigation regarding patents and other intellectual property rights. Our product candidates and other proprietary technologies we may develop may infringe existing or future patents owned by third parties. We may in the future become party to, or be threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our current and any future product candidates and technology, including interference proceedings, post grant review and inter partes review before the USPTO. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of their merit. There is a risk that third parties may choose to engage in litigation with us to enforce or to otherwise assert their patent rights against us. Even if we believe such claims are without merit, a court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, which could have a negative impact on our ability to commercialize our current and any future product candidates. In order to successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. If we are found to infringe a third party's valid and enforceable intellectual property rights, we could be required to obtain a license from such third party to continue developing, manufacturing and marketing our product candidate(s) and technology. 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 and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. We could be forced, including by court order, to cease developing, manufacturing and commercializing the infringing technology or product candidate. 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 or other intellectual property right. A finding of infringement could prevent us from manufacturing and commercializing our current or any future product candidates or force us to cease some or all 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, financial condition, results of operations and prospects.

Third parties asserting their patent or other intellectual property rights against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our product candidates or force us to cease some of our business operations. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of management and other employee resources from our business, cause development delays, and may impact our reputation. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties, or redesign our infringing products, which may be impossible on a cost-effective basis or require substantial time and monetary expenditure. In that event, we would be unable to further develop and commercialize our product candidates, which could harm our business significantly. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

We are aware of third-party patents and/or patent applications that could adversely affect the potential commercialization of our compounds. For example, we are aware of third-party patents, as well as a third-party patent application, with broad claims to administering an S1P receptor modulator by starting with a lower dose and then increasing to a higher, standard daily dose. Further, we are aware of third-party patent applications with broad claims to administering a 5-HT receptor agonist for epileptic disorders. While we do not believe that any such claims that would cover the potential commercialization of LP352 or LP659 would be valid and enforceable, we may be incorrect in this belief.

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

Competitors may infringe or otherwise violate our patents, the patents of our licensors or our other intellectual property rights. To counter infringement or unauthorized use, we may be required to file legal claims, which can be expensive, time-consuming, and unpredictable. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our related patent applications at risk of not issuing. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. The initiation of a claim against a third party may also cause the third party to bring counter claims against us such as claims asserting that our patents are invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement or lack of statutory subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant material information from the USPTO, or made a materially misleading statement, during prosecution. Third parties may also raise similar validity claims before the USPTO in post-grant proceedings such as ex parte reexaminations, inter partes review, or post-grant review, or oppositions or similar proceedings outside the United States, in parallel with litigation or even outside the context of litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. We cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. For the patents and patent applications that we have licensed, we may have limited or no right to participate in the defense of any licensed patents against challenge by a third party. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of any future patent protection on our current or future product candidates. Such a loss of patent protection could harm our business.

Interference or derivation proceedings provoked by third parties or brought by the USPTO may be necessary to determine the priority of inventions with respect to, or the correct inventorship of, our patents or patent applications or those of our licensors. An unfavorable outcome could result in a loss of our current patent rights and could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Litigation, interference, derivation or other proceedings may result in a decision adverse to our interests and, even if we are successful, may result in substantial costs and distract our management and other employees.

There may be third-party patents of which we are currently unaware with 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 and other proprietary technologies we may develop, could be found to be infringed by our product candidate. 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. In addition, our competitors in both the United States and abroad, many of which have made substantial investments in patent portfolios and competing technologies, may obtain patents in the future that may prevent, limit or otherwise interfere with our ability to make, use and sell our product candidates, and may claim that use of our technologies or the manufacture, use, or sale of our product candidates infringes upon these patents. We may also receive, and expect to receive, communications from various industry participants alleging our infringement of their patents, trade secrets or other intellectual property rights and/or offering licenses to such intellectual property.

We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Our business could be harmed if in litigation the prevailing party does not offer us a license on commercially reasonable terms. Any litigation or other proceedings to enforce our intellectual property rights may fail, and even if successful, may result in substantial costs and distract our management and other employees.

Because of the expense and uncertainty of litigation, we may conclude that even if a third-party is infringing our issued patents, or any patents that may be issued as a result of our pending or future patent applications or other intellectual property rights, the risk-adjusted cost of bringing and enforcing such a claim or action, which typically last for years before they are concluded, may be too high or not in the best interest of our company or our stockholders, or it may be otherwise impractical or undesirable to enforce our intellectual property against some third parties. Our competitors or other third parties may be able to sustain the costs of complex patent litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. In such cases, we may decide that the 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 and that the more prudent course of action is to simply monitor the situation or initiate or seek some other non-litigious action or solution. In addition, the uncertainties associated with litigation could compromise our ability to raise the funds necessary to continue our clinical

trials, continue our internal research programs, in-license needed technology or other product candidates, or enter into development partnerships that would help us bring our product candidates to market.

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 this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have an adverse effect on the price of our common stock.

Issued patents covering our product candidates could be found invalid or unenforceable if challenged in court or before the USPTO or comparable foreign authority.

If we or one of our licensing partners initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim we infringe their patents or that the patent covering our product candidate is invalid or unenforceable, or both. In any patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention, or decide that the other party's use of our patented technology falls under the safe harbor to patent infringement under 35 U.S.C. §271(e)(1). With respect to the validity of our patents, for example, we cannot be certain that there is no invalidating prior art of which we, our patent counsel, and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates and such an outcome may limit our ability to assert our patents against those parties or other competitors and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Such a loss of patent protection could have a material adverse impact on our business. 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.

Changes in U.S. patent law or the patent law of other countries or jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our current and any future product candidates.

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. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we have licensed or that we might obtain in the future. Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we have licensed or that we may obtain in the future.

We may not be able to protect our intellectual property rights throughout the world, which could negatively impact our business.

Filing, prosecuting and defending patents covering our current and any future product candidates throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can have a different scope and strength than do those in the United States. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own drugs and, further, may export otherwise infringing drugs to territories where we may obtain patent protection, but where patent enforcement is not as strong as that in the United States. These drugs may compete with our drugs in jurisdictions where we do not have any issued or licensed patents and any future patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property, particularly those relating to biopharmaceutical products, which could make it difficult in those jurisdictions for us to stop the infringement or misappropriation of our patents or other intellectual property rights, or the marketing of competing products in violation of our proprietary rights. Proceedings to enforce our patent and other intellectual property rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business. Furthermore, such proceedings could put our patents at risk of being invalidated, held unenforceable, or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims of infringement or

misappropriation against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Similarly, if our trade secrets are disclosed in a foreign jurisdiction, competitors worldwide could have access to our proprietary information and we may be without satisfactory recourse. Such disclosure could have a material adverse effect on our business. Moreover, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws. In addition, certain developing countries, including China and India, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we and our licensors may have limited remedies if patents are infringed or if we or our licensors are compelled to grant a license to a third party, which could materially diminish the value of those patents. In addition, many countries limit the enforceability of patents against government agencies or government contractors. This could limit our potential revenue opportunities. 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.

Reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

If we rely on third parties to manufacture or commercialize our current or any future product candidates, or if we collaborate with additional third parties for the development of our current or any future product candidates, we must, at times, share trade secrets with them. We may also conduct joint research and development programs that may require us to share trade secrets under the terms of our research and development partnerships or similar agreements. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, services agreements, consulting agreements or other similar agreements with our advisors, employees, third-party contractors and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure could have an adverse effect on our business and results of operations.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any third-party collaborators. A competitor's discovery of our trade secrets could harm our business.

Confidentiality agreements with employees and third parties may not prevent unauthorized disclosure of trade secrets and other proprietary information.

In addition to the protection afforded by patents, we seek to 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 product candidates, technology and product discovery and development processes that involve proprietary know-how, information, or technology that is not covered by patents. Any disclosure, either intentional or unintentional, by our employees, the employees of third parties with whom we share our facilities or third-party consultants and vendors that we engage to perform research, clinical trials or manufacturing activities, or misappropriation by third parties (such as through a cybersecurity breach) of our trade secrets or proprietary information could enable competitors to duplicate or surpass our technological achievements, thus eroding our competitive position in our market. Because we expect to rely on third parties in the development and manufacture of our product candidates, we must, at times, share trade secrets with them. Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Trade secrets and confidential information, however, may be difficult to protect. We seek to protect our trade secrets, know-how and confidential information, including our proprietary processes, in part, by entering into confidentiality agreements with our employees, consultants, outside scientific advisors, contractors, and collaborators. With our consultants, contractors, and outside scientific collaborators, these agreements typically include invention assignment obligations. We cannot guarantee that we have entered into such agreements with each party that may have or has had access to our trade secrets or proprietary technology and processes, or that any such agreements will be adequate. Although we seek to protect our trade secrets, our employees, consultants, outside scientific advisors, contractors, and collaborators might intentionally or inadvertently disclose our trade secret information to competitors or otherwise misappropriate our information, and in certain cases third parties who we may share confidential information have negotiated limits on their liability in their agreements with us. In addition, competitors may otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive

and time-consuming, and the outcome is unpredictable. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third-party, we would have no right to prevent them from using that technology or information to compete with us. Furthermore, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, or misappropriation of our intellectual property by third parties, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, operating results, and financial condition.

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

Many of our employees, consultants, and advisors are currently or were previously employed at universities or other healthcare, 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 we or these individuals 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 or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

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

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

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

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. 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, which may negatively impact our ability to market our products. We may incorrectly determine that our products 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, which may negatively impact our ability to develop and market our product candidates. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products.

One aspect of the determination of patentability of our inventions depends on the scope and content of the "prior art," information that was or is deemed available to a person of skill in the relevant art prior to the priority date of the claimed invention.

There may be prior art of which we are not aware that may affect the patentability of our patent claims or, if issued, affect the validity or enforceability of a patent claim. Further, we may not be aware of all third-party intellectual property rights potentially relating to our product candidates or their intended uses, and as a result the impact of such third-party intellectual property rights upon the patentability of our own patents and patent applications, as well as the impact of such third-party intellectual property upon our freedom to operate, is highly uncertain. Because patent applications in the United States and most other countries are confidential for typically a period of 18 months after filing, or may not be published at all, we cannot be certain that we were the first to file any patent application related to our product candidates. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Furthermore, for U.S. applications in which all claims are entitled to a priority date before March 16, 2013, an interference proceeding can be provoked by a third party or instituted by the USPTO to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. For U.S. applications containing a claim not entitled to priority before March 16, 2013, there is a greater level of uncertainty in the patent law in view of the passage of the America Invents Act, which brought into effect significant changes to the U.S. patent laws, including new procedures for challenging pending patent applications and issued patents.

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

Our trademarks or trade names may be challenged, opposed, infringed, circumvented, invalidated, cancelled, declared generic, determined to be not entitled to registration, or determined to be infringing on other marks. During trademark registration proceedings, we may receive rejections of our applications by the USPTO or in foreign jurisdictions. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. Any trademark litigation could be expensive. In addition, we could be found liable for significant monetary damages, including treble damages, disgorgement of profits and attorneys' fees, if we are found to have willfully infringed a trademark. We may not be able to protect our exclusive right to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential collaborators or customers in our markets of interest. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected. We may license our trademarks and trade names to third parties, such as distributors. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names.

Risks Related to Our Dependence on Third Parties or Their Actions

We do not have our own manufacturing capabilities and will rely on third parties to produce clinical and commercial supplies of our current and any future product candidates. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We have no experience in drug formulation or manufacturing and do not own or operate, and we do not expect to own or operate, facilities for drug manufacturing, storage and distribution, or testing. We will be dependent on third parties to manufacture the clinical supplies of our product candidates.

Further, we also will rely on third-party manufacturers to supply us with sufficient quantities of our product candidates, to be used, if approved, for commercialization. We do not have long-term supply agreements or commitments with a manufacturer to produce raw materials, active pharmaceutical ingredients and the finished products of our product candidates or the associated packaging. Furthermore, the raw materials for our product candidates are sourced, in some cases, from a single-source supplier. If we were to experience an unexpected loss of supply of any of our product candidates or any of our future product candidates for any reason, whether as a result of manufacturing, supply or storage issues or otherwise, we could experience delays, disruptions, suspensions or terminations of, or be required to restart or repeat, any pending or ongoing clinical trials. For example, the extent to which adverse macroeconomic or geopolitical developments such as the COVID-19 or another pandemic, or the ongoing conflict between Russia and Ukraine, impacts our ability to procure sufficient supplies for the development of our products and product candidates will depend on the severity and duration of the spread of the virus, and the actions undertaken to contain the virus or treat its effects. Any significant delay in the supply of a product candidate, or the raw material components thereof, for an ongoing clinical trial due to the need to replace a third-party manufacturer could considerably delay completion of our clinical trials, product testing and potential regulatory approval of our product candidates.

Our reliance on third-party manufacturers entails various risks, some of which we would not be subject if we manufactured product candidates ourselves, including:

- inability to meet our drug specifications and quality requirements consistently;
- delay or inability to procure or expand sufficient manufacturing capacity;
- issues related to scale-up of manufacturing;
- costs and validation of new equipment and facilities required for scale-up;
- failure to comply with cGMP or similar foreign standards;
- inability to negotiate manufacturing agreements with third parties under commercially reasonable terms, if at all;
- termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us;
- reliance on single sources for drug components;
- lack of qualified backup suppliers for those components that are currently purchased from a sole or single source supplier;
- misappropriation of proprietary information, including our trade secrets and know-how;
- the mislabeling of clinical supplies, potentially resulting in the wrong dose amounts being supplied or study drug or placebo not being properly identified;
- clinical supplies not being delivered to clinical sites on time, leading to clinical trial interruptions, or of drug supplies not being distributed to commercial vendors in a timely manner, resulting in lost sales;
- operations of our third-party manufacturers or suppliers could be disrupted by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier; and
- carrier disruptions or increased costs that are beyond our control.

We do not have complete control over all aspects of the manufacturing process of, and are dependent on, our contract manufacturing partners for compliance with cGMP regulations for manufacturing both active drug substances and finished drug products. Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside of the United States. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA others, they will not be able to secure and/or maintain marketing approval for their manufacturing facilities. In addition, we do not have control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain marketing approval for or market our product candidates, if approved. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates or drugs and harm our business and results of operations.

Our current and anticipated future dependence upon others for the manufacture of our product candidates or drugs may adversely affect our future profit margins and our ability to commercialize any product candidates that receive marketing approval on a timely and competitive basis.

We intend to rely on third parties to conduct, supervise and monitor our preclinical studies and clinical trials, and if those third parties perform in an unsatisfactory manner, it may harm our business.

We do not currently have the ability to independently conduct preclinical studies or clinical trials required to develop our drug candidates. We intend to rely on CROs, clinical trial sites and other third parties to ensure the proper and timely conduct of our preclinical studies and clinical trials, and we expect to have limited influence over their actual performance. We intend to rely upon CROs and others to monitor and manage data for our clinical programs, as well as the execution of future nonclinical studies. We expect to control only certain aspects of our CROs' and others' activities. Nevertheless, we will be responsible for ensuring that each of our preclinical studies or clinical trials are conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on the CROs and others does not relieve us of our regulatory responsibilities.

We, our CROs and other third parties we might engage will be required to comply with the GLPs and GCPs, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities in the form of International Conference on Harmonization guidelines for any of our product candidates that are in preclinical and clinical development. The regulatory

authorities enforce GCPs through periodic inspections of trial sponsors, principal investigators and clinical trial sites. Although we will rely on CROs and others to conduct GCP-compliant clinical trials, we remain responsible for ensuring that each of our GLP preclinical studies and clinical trials is conducted in accordance with its investigational plan and protocol and applicable laws and regulations, and our reliance on the CROs and others does not relieve us of our regulatory responsibilities. If we, our CROs and other third parties we engage fail to comply with GCPs, 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 before approving our marketing applications. Accordingly, if our CROs or others fail to comply with these regulations or fail to recruit a sufficient number of participants, we may be required to repeat clinical trials, which would delay the regulatory approval process.

While we will have agreements governing their activities, our CROs and other third parties we engage will not be our employees, and we will not control whether or not they devote sufficient time and resources to our future clinical and nonclinical programs. These CROs and others may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials, or other drug development activities which could harm our business. We face the risk of potential unauthorized disclosure or misappropriation of our intellectual property by CROs and others, which may reduce our trade secret protection and allow our potential competitors to access and exploit our proprietary technology. In addition, certain of our agreements with CROs and other third parties provide for monetary and other limitations on their liability. If our CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for any other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize any product candidate that we develop. As a result, our financial results and the commercial prospects for any product candidate that we develop would be harmed, our costs could increase, and our ability to generate revenue could be delayed, decreased or eliminated.

If our relationship with these CROs terminates, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. Switching or adding additional CROs involves substantial cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can negatively impact our ability to meet our desired clinical development timelines. Though we intend to carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a negative impact on our business, financial condition and prospects.

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 a principal investigator has created a conflict of interest or otherwise affected interpretation of the trial. 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 marketing approval of our current and future product candidates.

If we or our third-party manufacturers use hazardous and biological materials in a manner that causes injury or violates applicable law, we may be liable for damages.

Our research and development activities involve the controlled use of potentially hazardous substances, including chemical and biological materials, by our third-party manufacturers. Our manufacturers are subject to federal, state, and local laws and regulations in the United States governing the use, manufacture, storage, handling and disposal of medical, radioactive and hazardous materials. Although we believe that our manufacturers' procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of contamination or injury resulting from medical, radioactive or hazardous materials. As a result of any such contamination or injury, we may incur liability or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do not have any insurance for liabilities arising from medical radioactive or hazardous materials. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development, and production efforts, which could harm our business, prospects, financial condition, or results of operations.

Arena was acquired by Pfizer on March 11, 2022, and Arena's acquisition may negatively impact our development programs and stock price.

On March 11, 2022, Pfizer announced it completed its acquisition of Arena, and Arena became a wholly-owned subsidiary of Pfizer. We have licensed our product candidates, including LP352 and LP659, from Arena under the Arena License Agreement, and we will rely on Arena to help protect intellectual property relating to our licensed products. Arena also holds a substantial percentage of our outstanding shares of common stock. We do not know if Pfizer will cooperate with us in protecting the intellectual property

relating to our licensed products or hold or sell the shares of our common stock that it owns. We also do not know if Pfizer will view our development programs positively or negatively, or as complimentary or competitive to its development programs. We are also entitled to receive information and milestones and royalty payments under the Royalty Purchase Agreement. If a disagreement between us and Pfizer were to occur, Pfizer might challenge our rights or default on its obligations in the Arena License Agreement, the Royalty Purchase Agreement or another agreement between us, or sell its shares, any of which actions could have an adverse impact on our ability to develop our licensed products or on our stock price.

Risks Related to Our Business Operations, Employee Matters and Managing Growth

We are highly dependent on the services of our senior management team and if we are not able to retain these members of our management team and recruit and retain additional management, clinical and scientific personnel, our business will be harmed.

We are highly dependent on our senior management team. The employment agreements we have with these officers do not prevent such persons from terminating their employment with us at any time. The loss of the services of any of these persons could impede the achievement of our research, development and commercialization objectives.

In addition, we will need to attract, retain and motivate highly qualified additional management, clinical and scientific personnel. If we are not able to retain our management and to attract, on acceptable terms, additional qualified personnel necessary for the continued development of our business, we may not be able to sustain our operations or grow.

We may not be able to attract or retain qualified personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses. Many of the other pharmaceutical companies that we compete against for qualified personnel and consultants have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high-quality candidates and consultants than what we have to offer. This competition has become exacerbated by the increase in employee resignations currently taking place throughout the United States as a result of the COVID-19 pandemic, which is commonly referred to as the "great resignation." We may also experience employee turnover as a result of the ongoing "great resignation." In response to competition and adverse macroeconomic and geopolitical developments, including rising inflation rates and labor shortages, we may need to adjust employee cash compensation, which would affect our operating costs and our margins, or equity compensation, which would affect our outstanding share count and cause dilution to existing stockholders. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. If we are unable to continue to attract, retain and motivate high-quality personnel and consultants to accomplish our business objectives, the rate and success at which we can discover and develop product candidates and our business will be limited and we may experience constraints on our development objectives.

Our future performance will also depend, in part, on our ability to successfully integrate newly hired executive officers into our management team and our ability to develop an effective working relationship among senior management. Our failure to integrate these individuals and create effective working relationships among them and other members of management could result in inefficiencies in the development and commercialization of our product candidates, harming future regulatory approvals, sales of our product candidates and our results of operations. Additionally, we do not currently maintain "key person" life insurance on the lives of our executives or any of our employees.

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

We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, operational inefficiencies, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of our current and potential future product candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and grow revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance, our ability to commercialize product candidates, develop a scalable infrastructure and compete effectively will depend, in part, on our ability to effectively manage any future growth.

Our employees, principal investigators, consultants and commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of fraud or other misconduct by our employees, independent contractors, CROs, principal investigators, consultants and commercial partners. Misconduct by these parties could include intentional failures to comply with FDA regulations or the regulations applicable in other jurisdictions, provide accurate information to the FDA and other regulatory authorities, comply with manufacturing standards, comply with healthcare fraud and abuse laws and regulations in the United States

and abroad, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct also could involve the improper use of information obtained in the course of clinical trials or interactions with the FDA or other regulatory authorities, which could result in regulatory sanctions and cause serious harm to our reputation. If we obtain regulatory approval for any of our product candidates and begin commercializing those products, our potential exposure under such laws will increase significantly, and our costs associated with compliance with such laws are also likely to increase. 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 government investigations or other actions or lawsuits stemming from a failure to comply with these 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 negative impact on our business, financial condition, results of operations and prospects, including the imposition of significant civil, criminal and administrative penalties, damages, disgorgement, monetary fines, imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, additional reporting requirements and/or oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations.

COVID-19 has impacted and could continue to adversely impact our business.

Our business has been and could continue to be adversely affected by the global COVID-19 pandemic. As a result of the COVID-19 pandemic, we have faced and may continue to face delays in meeting our anticipated timelines for our ongoing and planned clinical trials. Specifically, the initiation of the MAD portion of the Phase 1 clinical trial of LP352 was delayed, in part, as a result of the impact of the COVID-19 pandemic on the clinical site in the United Kingdom that conducted the SAD portion of the Phase 1 clinical trial for LP352, and subsequently we modified the protocol and relocated the MAD portion of such trial to a new clinical site in the United States. We completed the MAD portion in September 2021. The extent to which the COVID-19 pandemic continues to impacts our business, our clinical development and regulatory efforts will depend on future developments that are highly uncertain and cannot be predicted with confidence, such as the duration of the outbreak, and the emergence of new strains or variants of the virus, vaccine shortages and administration rates, the effectiveness of government policies, including travel restrictions, quarantines, social distancing and vaccine mandate requirements, and business closures in the United States and other countries, and business disruptions, and the effectiveness of actions taken in the United States and other countries to contain and treat the virus and its variants. Accordingly, we do not yet know the full extent of potential delays or impacts on our business, our clinical and regulatory activities, healthcare systems or the global economy as a whole. However, these impacts have previously impacted and could in the future adversely affect our business, financial condition, results of operations and growth prospects.

In addition, to the extent the ongoing COVID-19 pandemic adversely affects our business and results of operations, it may also have the effect of heightening many of the other risks and uncertainties described in this “Risk Factors” section.

Risks Related to Ownership of Our Common Stock

An active, liquid and orderly trading market for our common stock may not be sustained.

We have a limited number of shares that trade each day compared to many other companies. You may not be able to sell your shares quickly or at the market price if trading in shares of our common stock is not active.

Further, a lesser active market may impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic partnerships or acquire companies or products by using our shares of common stock as consideration.

The price of our stock may be volatile, and you could lose all or part of your investment.

The trading price of our common stock may be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. For example, the closing price of our common stock from January 1, 2022 to February 28, 2023 has ranged from a low of $2.95 to a high of $6.00. In addition to the factors discussed in this “Risk Factors” section and elsewhere in this Annual Report, these factors include:

- the commencement, enrollment or results of our ongoing and planned preclinical studies and clinical trials, or any future pre-clinical studies or clinical trials, we may conduct of our current and any future product candidates, or changes in the development status of our current and any future product candidates;

- any delay in our regulatory filings for our current and any future product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including without limitation the FDA's issuance of a "refusal to file" letter or a request for additional information;
- adverse results or delays in our preclinical studies and clinical trials, including as a result of the FDA or comparable foreign regulatory authorities disagreeing with the design or implementation of our clinical trials;
- our decision to initiate a clinical trial, not to initiate a clinical trial, or to terminate an existing clinical trial;
- adverse regulatory decisions, including failure to receive regulatory approval for our current and any future product candidates;
- changes in laws or regulations applicable to our current and any future product candidates, including but not limited to clinical trial requirements for approvals;
- the failure to obtain coverage and adequate reimbursement of our current and any future product candidates, if approved;
- changes on the structure of healthcare payment systems;
- any changes to our relationship with any manufacturers, suppliers, licensors, future collaborators or other strategic partners;
- our inability to obtain adequate product supply for any approved drug product or inability to do so at acceptable prices;
- our inability to establish collaborations if needed;
- our failure to commercialize our current and any future product candidates;
- any termination or loss of rights under the Arena License Agreement or Royalty Purchase Agreement;
- additions or departures of key scientific or management personnel;
- unanticipated serious safety concerns related to the use of our current and any future product candidates;
- introduction of new products or services offered by us or our competitors, or the release or publication of clinical trial results from competing product candidates;
- announcements of significant acquisitions, strategic partnerships, joint ventures, or capital commitments by us or our competitors;
- our ability to effectively manage our growth;
- actual or anticipated variations in quarterly operating results;
- our cash position;
- our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- changes in the market valuations of similar companies;
- overall performance of the equity markets;
- issuances of debt or equity securities;
- sales of our common stock by us or our stockholders in the future, including sales of our common stock by Arena, or the perception that such sales may occur;
- trading volume of our common stock;
- changes in accounting practices;
- ineffectiveness of our internal controls;
- disputes or other developments relating to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies;
- significant lawsuits, including patent or stockholder litigation;

- geopolitical and macroeconomic conditions, including the COVID-19 pandemic, the conflict in Ukraine, economic slowdowns, recessions, inflation, rising interest rates and tightening of credit markets; and
- other events or factors, many of which are beyond our control.

In addition, the stock market in general, and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources, which would harm our business, operating results or financial condition.

We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock.

We have never declared or paid any cash dividend on our common stock. We currently anticipate that we will retain future earnings for the development, operation, and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders would therefore be limited to the appreciation, if any, of their stock.

Our principal stockholders and management own a significant percentage of our stock and are able to exert significant control over matters subject to stockholder approval. Our stock market price may be negatively affected if our principal stockholders and management sell some or all of their stock.

Our executive officers, directors, greater than 5% holders, and their affiliates beneficially own shares representing a significant percentage of our common stock. These stockholders will have the ability to influence us through their ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders.

The dual class structure of our common stock may limit your ability to influence corporate matters and may limit your visibility with respect to certain transactions.

The dual class structure of our common stock may limit your ability to influence corporate matters. Holders of our common stock are entitled to one vote per share, while holders of our non-voting common stock are not entitled to any votes. Nonetheless, each share of our non-voting common stock may be converted at any time into one share of our common stock at the option of its holder by providing written notice to us, subject to the limitations provided for in our amended and restated certificate of incorporation. Consequently, if holders of our non-voting common stock exercise their option to make this conversion, this will have the effect of increasing the relative voting power of those prior holders of our non-voting common stock, and correspondingly decreasing the voting power of the holders of our common stock, which may limit your ability to influence corporate matters. Additionally, stockholders who hold, in the aggregate, more than 10% of our common stock and non-voting common stock, but 10% or less of our common stock, and are not otherwise an insider, may not be required to report changes in their ownership due to transactions in our non-voting common stock pursuant to Section 16(a) of the Exchange Act, and may not be subject to the short-swing profit provisions of Section 16(b) of the Exchange Act.

Sales of a substantial number of shares of our common stock by our existing stockholders, including Arena (or Pfizer), in the public market, or the perception that such sales could occur, could cause our stock price to fall.

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, the trading price of our common stock could decline. As of December 31, 2022, there were a total of 13,585,950 shares of common stock outstanding, which does not include the shares of our non-voting common stock that may be converted into an aggregate of 3,629,400 shares of our common stock.

In addition, as of December 31, 2022, Arena (and Pfizer) owned 3,978,540 shares, or 23.1%, of our outstanding shares of voting and non-voting common stock. The sale by Arena (or Pfizer) of a substantial number of shares, or a perception that such sales could occur, could significantly reduce the market price of our common stock.

In addition, shares of common stock that are either subject to outstanding options or reserved for future issuance under our employee benefit plans will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, applicable lock-up agreements, and Rule 144 and Rule 701 under the Securities Act. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

Further, certain holders of shares of our common stock (including the shares of common stock issuable upon conversion of our non-voting common stock) are entitled to rights with respect to the registration of their shares under the Securities Act. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares held by affiliates, as defined in Rule 144 under the Securities Act. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to the Sales Agreement and our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

We expect that we will need significant additional capital in the future to continue our planned operations, including conducting clinical trials, commercialization efforts if we are able to obtain marketing approval of any of our current or future product candidates, research and development activities, and costs associated with operating a public company. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. For example, in September 2022, we entered into the Sales Agreement with Cantor Fitzgerald, pursuant to which we may issue and sell, from time to time, shares of common stock having an aggregate offering price of up to $20.0 million through Cantor Fitzgerald acting as the sales agent. We have not sold any shares of common stock under the Sales Agreement as of December 31, 2022. If we sell common stock, convertible securities or other equity securities, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights, preferences and privileges senior to the holders of our common stock.

Pursuant to our 2021 Equity Incentive Plan (2021 Plan), our management is authorized to grant stock options to our employees, directors and consultants. Additionally, the number of shares of our common stock reserved for issuance under our 2021 Plan will automatically increase on January 1 of each year, beginning on January 1, 2022 and continuing through and including January 1, 2031, by 5% of the total number of shares of our capital stock outstanding on December 31 of the preceding calendar year (determined on an as-converted to voting common stock basis, without regard to any limitations on the conversion of the non-voting common stock), or a lesser number of shares determined by our board of directors.

In addition, pursuant to our ESPP, the number of shares of our common stock reserved for issuance will automatically increase on January 1 of each calendar year, beginning on January 1, 2022 (through January 1, 2031), by the lesser of (i) 1% of the total number of shares of our common stock outstanding (determined on an as-converted to voting common stock basis, without regard to any limitations on the conversion of the non-voting common stock) on the last day of the fiscal year before the date of the automatic increase and (ii) such number of shares of common stock that would cause the aggregate number of shares of common stock then reserved for issuance under the ESPP to equal 1,060,017 shares; provided that before the date of any such increase, our board of directors may determine that such increase will be for a lesser amount of shares. Unless our board of directors elects not to increase the number of shares available for future grant each year, our stockholders may experience additional dilution, which could cause our stock price to fall.

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

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012 (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 not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002 (the Sarbanes-Oxley Act), reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding nonbinding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an emerging growth company until December 31, 2026, although circumstances could cause us to lose that status earlier, including if we become a “large accelerated filer” as defined in Rule 12b-2 under the Exchange Act or if we have total annual gross revenue of $1.235 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 following December 31 or, if we issue more than $1.0 billion in non-convertible debt during any three year period before that time, we would cease to be an emerging growth company immediately. Even after we no longer qualify as an emerging growth company, we may still qualify as a “smaller reporting company” which would allow us to take advantage of many of the same exemptions from disclosure requirements including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our

periodic reports and proxy statements. Investors may find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This provision allows an emerging growth company to delay the adoption of accounting standards that have different effective dates for public and private companies until those standards would otherwise apply to private companies. We have elected to avail ourselves of this exemption from new or revised accounting standards, and therefore we will not be subject to the same requirements to adopt new or revised accounting standards as other public companies that are not emerging growth companies.

We are also a "smaller reporting company" as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as our voting and non-voting common stock held by non-affiliates is less than $250.0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than $100.0 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter.

Delaware law and provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make a merger, tender offer or proxy contest difficult, thereby depressing the trading price of our common stock.

Provisions of our amended and restated certificate of incorporation and amended and restated bylaws may delay or discourage transactions involving an actual or potential change in our control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares or transactions that our stockholders might otherwise deem to be in their best interests. Therefore, these provisions could adversely affect the price of our common stock. Among other things, our amended and restated certificate of incorporation and amended and restated bylaws:

- permit our board of directors to issue up to 10,000,000 shares of preferred stock, with any rights, preferences and privileges as they may designate (including the right to approve an acquisition or other change in our control);
- provide that the authorized number of directors may be changed only by resolution of the board of directors;
- provide that our board of directors or any individual director may only be removed with cause and the affirmative vote of the holders of at least 66-2/3% of the voting power of all of our then-outstanding common stock;
- provide that all vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- divide our board of directors into three classes;
- require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent;
- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide notice in writing in a timely manner and also specify requirements as to the form and content of a stockholder's notice;
- do not provide for cumulative voting rights (therefore allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose);
- provide that special meetings of our stockholders may be called only by the chair of our board of directors, our Chief Executive Officer or by the board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors; and
- provide that the Court of Chancery of the State of Delaware is the sole and exclusive forum for the following types of actions or proceedings under state, statutory and common law: (i) any derivative action or proceeding brought on our behalf; (ii) any action or proceeding asserting a claim of breach of a fiduciary duty owed by any of our current or former directors, officers or other employees to us or our stockholders; (iii) any action or proceeding asserting a claim against us or any of our current or former directors, officers or other employees, arising out of or pursuant to any provision of the Delaware General Corporation Law, our certificate of incorporation or our bylaws; (iv) any action or proceeding to interpret, apply, enforce or determine the validity of our certificate of incorporation or our bylaws; (v) any action or proceeding as to which the Delaware General Corporation Law confers jurisdiction to the Court of Chancery of the State of Delaware; and (vi) any action asserting a claim against us or any of our 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; provided these provisions of our amended and restated certificate of incorporation and amended and restated bylaws do not apply to suits brought to enforce a duty or liability created by the Exchange Act, or any other claim for which the federal courts have exclusive jurisdiction; and provided 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 of America shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act, including all causes of action asserted against any defendant to such complaint. For the avoidance of doubt, this provision is intended to benefit and may be enforced by us, our officers and directors, the underwriters to any offering giving rise to such complaint, and any other professional or 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.

The amendment of any of these provisions, with the exception of the ability of our board of directors to issue shares of preferred stock and designate any rights, preferences and privileges thereto, would require approval by the holders of at least 66-2/3% of our then-outstanding common stock.

In addition, as a Delaware corporation, we are subject to Section 203 of the Delaware General Corporation Law. These provisions may prohibit large stockholders, in particular those owning 15% or more of our outstanding voting stock, from merging or combining with us for a certain period of time. A Delaware corporation may opt out of this provision by express provision in its original certificate of incorporation or by amendment to its certificate of incorporation or bylaws approved by its stockholders. However, we have not opted out of this provision.

These and other provisions in our amended and restated certificate of incorporation, amended and restated bylaws and Delaware law could make it more difficult for stockholders or potential acquirors to obtain control of our board of directors or initiate actions that are opposed by our then-current board of directors, including delay or impede a merger, tender offer or proxy contest involving our company. The existence of these provisions could negatively affect the price of our common stock and limit opportunities for you to realize value in a corporate transaction.

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

Our amended and restated certificate of incorporation provides that, to the fullest extent permitted by law and subject to the court's having personal jurisdiction over the indispensable parties named as defendants, the Court of Chancery of the State of Delaware is the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law:

- any derivative action or proceeding brought on our behalf;
- any action or proceeding asserting a breach of fiduciary duty owed by any of our current or former directors, officers or other employees to us or our stockholders;
- any action or proceeding asserting a claim against us or any of our current or former directors, officers or other employees arising out of or pursuant to any provision of the Delaware General Corporation Law, our certificate of incorporation or bylaws;
- any action or proceeding to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or our amended and restated bylaws;
- any action or proceeding as to which the Delaware General Corporation Law confers jurisdiction to the Court of Chancery of the State of Delaware; and
- any action asserting a claim against us or any of our directors, officers or other employees that is governed by the internal affairs doctrine.

This provision does not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation further provides that the federal district courts of the United States of America is the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation. This may require significant additional costs

associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions.

These exclusive forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees, which may discourage lawsuits against us and our directors, officers and other employees. If a court were to find either exclusive forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving the dispute in other jurisdictions, all of which could seriously harm our business.

General Risk Factors

We have incurred, and expect to continue to incur, significant increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.

As a public company, we have incurred and expect to continue to incur significant legal, accounting, and other expenses that we did not incur as a private company. We are subject to the reporting requirements of the Exchange Act, which require, among other things, that we file with the SEC annual, quarterly, and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC and Nasdaq to implement provisions of the Sarbanes-Oxley Act, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, in July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act) was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas such as "say on pay" and proxy access. Emerging growth companies and smaller reporting companies are exempted from certain of these requirements, but we may be required to implement these requirements sooner than budgeted or planned and thereby incur unexpected expenses. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

We expect the rules and regulations applicable to public companies to continue to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition, and results of operations. The increased costs will continue to decrease our net income or increase our net loss, and may require us to reduce costs in other areas of our business or increase the prices of our products or services. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain the same or similar coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

If we fail to maintain proper and effective internal control over financial reporting, our ability to produce accurate and timely financial statements could be impaired, investors may lose confidence in our financial reporting and the trading price of our common stock may decline.

Pursuant to Section 404 of Sarbanes-Oxley, our management are required to report upon the effectiveness of our internal control over financial reporting beginning with the annual report for our fiscal year ending December 31, 2022. When we lose our status as an "emerging growth company" and reach an accelerated filer threshold, our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for our management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. To comply with the requirements of being a reporting company under the Exchange Act, we will need to upgrade our information technology systems; implement additional financial and management controls, reporting systems and procedures; and hire additional accounting and finance staff. If we or, if required, our auditors are unable to conclude that our internal control over financial reporting is effective, investors may lose confidence in our financial reporting and the trading price of our common stock may decline.

We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness in our internal control over financial reporting once that firm begin its Section 404 reviews, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control

over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

We could be subject to securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biopharmaceutical companies have experienced significant stock price and volume volatility in recent years that have often been unrelated or disproportionate to the operating performance of these companies. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business, operating results or financial condition.

Our business could be negatively affected as a result of actions of activist stockholders, and such activism could impact the trading value of our securities.

Stockholders may, from time to time, engage in proxy solicitations or advance stockholder proposals, or otherwise attempt to effect changes and assert influence on our board of directors and management. Activist campaigns that contest or conflict with our strategic direction or seek changes in the composition of our board of directors could have an adverse effect on our operating results and financial condition. A proxy contest would require us to incur significant legal and advisory fees, proxy solicitation expenses and administrative and associated costs and require significant time and attention by our board of directors and management, diverting their attention from the pursuit of our business strategy. Any perceived uncertainties as to our future direction and control, our ability to execute on our strategy, or changes to the composition of our board of directors or senior management team arising from a proxy contest could lead to the perception of a change in the direction of our business or instability which may result in the loss of potential business opportunities, make it more difficult to pursue our strategic initiatives, or limit our ability to attract and retain qualified personnel and business partners, any of which could adversely affect our business and operating results. If individuals are ultimately elected to our board of directors with a specific agenda, it may adversely affect our ability to effectively implement our business strategy and create additional value for our stockholders. We may choose to initiate, or may become subject to, litigation as a result of the proxy contest or matters arising from the proxy contest, which would serve as a further distraction to our board of directors and management and would require us to incur significant additional costs. In addition, actions such as those described above could cause significant fluctuations in our stock price based upon temporary or speculative market perceptions or other factors that do not necessarily reflect the underlying fundamentals and prospects of our business.

Our failure to meet Nasdaq's continued listing requirements could result in a delisting of our common stock.

If we fail to satisfy the continued listing requirements of Nasdaq, such as the corporate governance requirements or the minimum closing bid price requirement, Nasdaq may take steps to delist our common stock. Such a delisting would likely have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. In the event of a delisting, we can provide no assurance that any action taken by us to restore compliance with listing requirements would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the Nasdaq minimum bid price requirement or prevent future non-compliance with the listing requirements of Nasdaq.

If securities or industry analysts publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who covers us downgrades our stock or publishes inaccurate or unfavorable research about our business, or discontinues coverage, our stock price may decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

Significant disruptions of our information technology systems or data security incidents could result in significant financial, legal, regulatory, business and reputational harm to us.

We are increasingly dependent on information technology systems and infrastructure, including mobile technologies, to operate our business. In the ordinary course of our business, we collect, store, process and transmit large amounts of sensitive information, including intellectual property, proprietary business information, personal information and other confidential information. We have also outsourced elements of our operations (including elements of our information technology infrastructure) to third parties, and as a result, we manage a number of third-party vendors who may have access to our computer networks or our confidential information. In addition, many of those third parties in turn subcontract or outsource some of their responsibilities to third parties. While all information technology operations are inherently vulnerable to inadvertent or intentional security breaches, incidents, attacks and

exposures, the accessibility and distributed nature of our information technology systems, and the sensitive information stored on those systems, make such systems potentially vulnerable to unintentional or malicious, internal and external attacks on our technology environment. In addition, due to the COVID-19 pandemic, we have enabled our employees to work remotely, which may make us more vulnerable to cyberattacks. Potential vulnerabilities can be exploited from inadvertent or intentional actions of our employees, third-party vendors, business partners, or by malicious third parties. Attacks of this nature are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives (including, but not limited to, industrial espionage) and expertise, including organized criminal groups, "hacktivists," nation states and others. In addition to the access to or extraction of sensitive information, such attacks could include the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information. In addition, the prevalent use of mobile devices increases the risk of data security incidents.

Significant disruptions of our, our third-party vendors' and/or business partners' information technology systems or other similar data security incidents could adversely affect our business operations and/or result in the loss, misappropriation, and/or unauthorized access, use or disclosure of, or the prevention of access to, sensitive information, which could result in financial, legal, regulatory, business and reputational harm to us. In addition, information technology system disruptions, whether from attacks on our technology environment or from computer viruses, natural disasters, terrorism, war and telecommunication and electrical failures, could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Additionally, theft of our intellectual property or proprietary business information could require substantial expenditures to remedy. If we or our third-party collaborators, consultants, contractors, suppliers, or service providers were to suffer an attack or breach, for example, that resulted in the unauthorized access to or use or disclosure of personal or health information, we may have to notify consumers, partners, collaborators, government authorities, and the media, and may be subject to investigations, civil penalties, administrative and enforcement actions, and litigation, any of which could harm our business and reputation.

There is no way of knowing with certainty whether we have experienced any data security incidents that have not been discovered. While we have no reason to believe this to be the case, attackers have become very sophisticated in the way they conceal access to systems, and many companies that have been attacked are not aware that they have been attacked. Any event that leads to unauthorized access, use or disclosure of personal information, including but not limited to personal information regarding our patients or employees, could disrupt our business, harm our reputation, compel us to comply with applicable federal and/or state breach notification laws and foreign law equivalents, subject us to time consuming, distracting and expensive litigation, regulatory investigation and oversight, mandatory corrective action, require us to verify the correctness of database contents, or otherwise subject us to liability under laws, regulations and contractual obligations, including those that protect the privacy and security of personal information. This could result in increased costs to us, and result in significant legal and financial exposure and/or reputational harm. In addition, any failure or perceived failure by us or our vendors or business partners to comply with our privacy, confidentiality or data security-related legal or other obligations to third parties, or any further security incidents or other inappropriate access events that result in the unauthorized access, release or transfer of sensitive information, which could include personally identifiable information, may result in governmental investigations, enforcement actions, regulatory fines, litigation, or public statements against us by advocacy groups or others, and could cause third parties, including clinical sites, regulators or current and potential partners, to lose trust in us or we could be subject to claims by third parties that we have breached our privacy- or confidentiality-related obligations, which could materially and adversely affect our business and prospects. Moreover, data security incidents and other inappropriate access can be difficult to detect, and any delay in identifying them may lead to increased harm of the type described above. While we have implemented security measures intended to protect our information technology systems and infrastructure, there can be no assurance that such measures will successfully prevent service interruptions or security incidents.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

In June 2021, we entered into a lease agreement for office space located at 4275 Executive Square, Suite 950, La Jolla, California 92037, where we occupy 8,681 square feet. The lease agreement will expire on December 31, 2024. We believe that the lease agreement for our corporate headquarters is adequate to meet our needs for the foreseeable future.

Item 3. Legal Proceedings.

From time to time, we may be involved in legal proceedings arising in the ordinary course of business. We believe there is no threatened litigation or litigation pending that could have, individually or in the aggregate, a material adverse effect on our financial position, results of operations or cash flows.

Item 4. Mine Safety Disclosures.

None.

PART II

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

Market Information

Our common stock has been traded on the Nasdaq Global Market under the symbol "LBPH" since March 12, 2021. Prior to that date, there was no public trading market for our common stock.

Holders of Common Stock

The last reported sale price of our common stock on February 28, 2023 as reported on the Nasdaq Global Market was $5.06. As of February 28, 2023, there were approximately three holders of record of our common stock, one of which was Cede & Co., a nominee for Depository Trust Company (DTC). All of the shares of our common stock held by brokerage firms, banks and other financial institutions as nominees for beneficial owners are deposited into participant accounts at DTC and are therefore considered to be held of record by Cede & Co. as one stockholder. The actual number of stockholders is greater than this number of record holders and includes stockholders who are beneficial owners but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividend Policy

We have never declared or paid any cash dividends on our common stock and do not expect to pay any dividends for the foreseeable future. We currently intend to retain any future earnings to fund the operation, development, and expansion of our business. Any future determination to pay dividends will be at the sole discretion of our Board of Directors and will depend upon several factors, including our results of operations, capital requirements, financial condition, future prospects, contractual arrangements, restrictions imposed by applicable law, and other factors our Board of Directors may deem relevant.

Securities Authorized for Issuance under Equity Compensation Plans

Information about our equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report.

Use of Proceeds

On March 16, 2021, we completed our IPO and sold 5,298,360 shares of our common stock (inclusive of 298,360 shares purchased in April 2021 pursuant to the underwriters' option to purchase additional shares) at a public offering price of $16.00 per share. The offer and sale of the shares of common stock in the IPO were registered pursuant to a Registration Statement on Form S-1, as amended (File No. 333-253329), that was declared effective on March 11, 2021.

There has been no material change in the intended use of proceeds from our IPO as described in our final prospectus, dated March 11, 2021 and filed with the SEC pursuant to Rule 424(b)(4) on March 12, 2021.

Recent Sales of Unregistered Equity Securities

None.

Purchases of Equity Securities by the Issuer and Affiliated Parties

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 audited financial statements and related notes included elsewhere in this Annual Report. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Annual Report, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. You should carefully read the "Risk Factors" section of this Annual Report to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements.

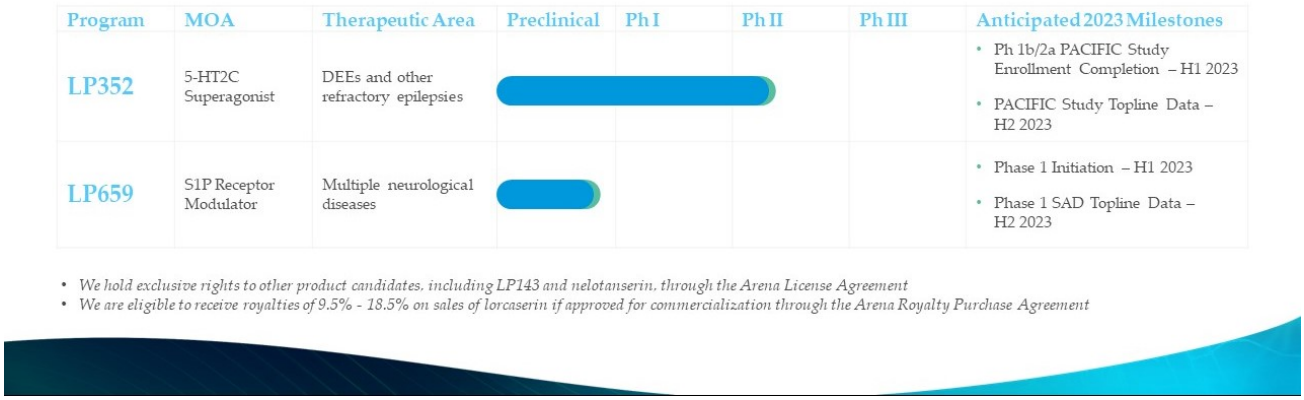
Overview

We are a clinical-stage biopharmaceutical company focused on developing novel, transformative medicines for neurological diseases. We were formed in January 2020 by Arena Pharmaceuticals, Inc. (Arena) to advance a portfolio of centrally acting product candidates designed to be highly selective for specific GPCRs. Our small molecule product candidates were discovered out of the same platform at Arena that represents a culmination of more than 20 years of world-class GPCR research. We are currently focused on developing the following product candidates in our pipeline:

- LP352, an oral, centrally acting, 5-hydroxytryptamine 2C receptor subtype, or 5-HT2C, superagonist, currently in a Phase 1b/2a clinical trial (the PACIFIC Study) expected to evaluate 50 participants ages 12 to 65 years old with developmental and epileptic encephalopathies, or DEEs, which may include Dravet syndrome, Lennox-Gastaut syndrome, tuberous sclerosis complex, CDKL5 deficiency disorder, SCN2A-related disorders, among others, with study enrollment expected to be completed in the first half of 2023 and topline data expected in the second half of 2023; and
- LP659, a centrally acting, sphingosine-1-phosphate, or S1P, receptor subtypes 1 and 5 modulator, for which the Company anticipates initiating a Phase 1 clinical study in healthy volunteers in the first half of 2023 and anticipates topline single ascending dose data in the second half of 2023.

In October 2020, we entered into a License Agreement with Arena (Arena License Agreement), pursuant to which Arena granted us an exclusive, royalty bearing, sublicensable, worldwide license to develop and commercialize LP352, LP659, LP143 and certain 5-HT2A compounds (pharmaceutical products containing any such compounds, the Licensed Products). In January 2022, we amended the Arena License Agreement to add an additional program, and in September 2022 we further amended the Arena License Agreement to expand the field of the license of LP659 and provide Arena a right of first negotiation to acquire certain development and commercial rights to LP659 products.

The following table provides an overview of our product candidates currently in development:



In addition to LP352 and LP659, we plan to continue to identify and develop other clinically differentiated product candidates for neurological diseases with high unmet medical need.

We are also eligible to receive royalties of 9.5% to 18.5% on sales of lorcaserin if approved for commercialization through the Royalty Purchase Agreement (as defined below).

We were incorporated in January 2020. Since our inception, we have devoted substantially all of our resources to organizing and staffing our company, research and development activities, business planning, raising capital, in-licensing intellectual property rights and establishing our intellectual property portfolio, and providing general and administrative support for these operations. We have principally financed our operations to date through the private placement of convertible preferred stock and public issuances and sales of our common stock. To date, we have raised gross proceeds of approximately $56.0 million from the issuance of our convertible preferred stock in October 2020, $84.8 million from our IPO in March 2021 and $23.0 million from our follow-on public offering in February 2023. As of December 31, 2022, we had cash, cash equivalents and short-term investments of $67.6 million.

We have incurred net losses since our inception. Our net losses were $43.9 million and $27.8 million for the years ended December 31, 2022 and 2021, respectively. As of December 31, 2022, we had an accumulated deficit of $86.1 million. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our clinical trials and preclinical studies and our expenditures on other research and development activities. We expect that our expenses and operating losses will increase substantially as product candidates advance through preclinical studies and clinical trials, and as we expand our clinical, regulatory, quality and manufacturing capabilities, incur significant commercialization expenses for marketing, sales, manufacturing and distribution, if we obtain marketing approval for any of our product candidates, and incur additional costs associated with operating as a public company. We expect that our existing cash, cash equivalents and short-term investments, along with proceeds from the follow-on public offering completed in February 2023, will be sufficient to fund our operations for at least the next 12 months. However, our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially. We base our estimate on assumptions that may prove to be wrong, and we could deplete our capital resources sooner than we expect.

We do not expect to generate any revenues from product sales unless and until we successfully complete development and obtain regulatory approval for one or more product candidates, which will not be for many years, if ever. Accordingly, until such time as we can generate significant revenue from sales of our product candidates, if ever, we expect to finance our cash needs through a combination of public or private equity offerings, debt financings, or other capital sources, including potential collaborations, licenses and other similar arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our failure to raise capital or enter into such other arrangements when needed would have a negative impact on our financial condition and could force us to delay, limit, reduce or terminate our research and development programs, future commercialization efforts or other operations, or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves, which would have a negative impact on our financial condition.

The global COVID-19 pandemic continues to evolve. As a result of the COVID-19 pandemic, we have faced and may continue to face delays in meeting our anticipated timelines for our ongoing and planned clinical trials. For example, the initiation of the multiple-ascending dose (MAD) portion of the Phase 1 clinical trial of LP352 was previously delayed, in part, as a result of the impact of the COVID-19 pandemic on the clinical site in the United Kingdom that conducted the single-ascending dose (SAD) portion of the Phase 1 clinical trial for LP352, and subsequently we modified the protocol and relocated the MAD portion of such trial to a new clinical site in the United States. We completed the MAD portion of the Phase 1 clinical trial of LP352 in September 2021. The extent of the impact of COVID-19 on our business, operations and development timelines and plans remains uncertain, and will depend on certain developments, including the duration and spread of the outbreak and its impact on our development activities, planned clinical trial enrollment, future trial sites, contract research organizations (CROs), third-party manufacturers, and other third parties with whom we do business, as well as its impact on regulatory authorities and our key scientific and management personnel. To the extent possible, we are conducting business as usual, with necessary or advisable modifications to employee travel and work locations. We will continue to actively monitor the evolving impacts of the COVID-19 pandemic and may take further actions that alter our operations, including those that may be required by federal, state or local authorities, or that we determine are in the best interests of our employees and other third parties with whom we do business. The extent to which the COVID-19 pandemic or a similar health epidemic may affect our business, operations and development timelines and plans, including the resulting impact on our expenditures and capital needs, remains highly uncertain and subject to change. For a discussion of risks related to the impact of the ongoing COVID-19 pandemic on our business, see Part II, Item 1A, "Risk Factors—Risks Related to Our Business Operations, Employee Matters and Managing Growth—COVID-19 has impacted and could continue to adversely impact our business."

In addition, the ongoing geopolitical turmoil caused by the conflict in Ukraine has contributed to further disruption, instability and volatility of the financial markets, which may have an adverse impact on our business or ability to access the capital markets in the future. For a discussion of risks related to the impact of the ongoing conflict in Ukraine on our business, see Part II, Item 1A, "Risk Factors—Risks Related to Our Limited Operating History, Financial Position and Need For Additional Capital—We will need substantial additional capital to finance our operations, which may not be available on acceptable terms, or at all. A recession or other unfavorable market conditions, including economic slowdowns, recessions, inflation, rising interest rates and tightening of credit markets caused by the ongoing COVID-19 pandemic, the conflict in Ukraine or otherwise, may limit our access to capital. Failure to

obtain this necessary capital when needed may force us to delay, limit or terminate certain of our product development efforts or other operations."

Agreements with Arena

Below is a summary of the key terms for our license and other agreements with Arena.

License Agreement

In October 2020, we entered into the Arena License Agreement, pursuant to which we obtained an exclusive, royalty bearing, sublicensable, worldwide license of certain intellectual property for the Licensed Products. In January 2022, we amended the Arena License Agreement to add an additional program, and in September 2022 we further amended the Arena License Agreement to expand the field of the license of LP659 and provide Arena a right of first negotiation to acquire certain development and commercial rights to LP659 products. The Arena License Agreement imposes various development, regulatory and/or commercial diligence obligations on our company, and requires the payment of royalties, including a mid-single digit royalty on net sales of Licensed Products of LP352, and a low-single digit royalty on net sales of all other Licensed Products, by our company, its affiliates or its sublicensees, subject to standard reductions, and other obligations.

Royalty Purchase Agreement

In October 2020, we entered into a Royalty Purchase Agreement (Royalty Purchase Agreement) with Arena and 356 Royalty Inc., a wholly owned subsidiary of Arena (356 Royalty), pursuant to which we purchased the right to receive all milestone payments, royalties, interest and other payments relating to net sales of lorcaserin, in all countries and territories of the world owed or otherwise payable to 356 Royalty by Eisai Inc. and Eisai Co., Ltd. (Eisai), pursuant to a Transaction Agreement dated December 28, 2016, as amended (Transaction Agreement), by and among 356 Royalty and Eisai for an upfront payment of approximately $0.1 million. Under the Transaction Agreement, the royalty rates range from 9.5% on annual global net sales less than or equal to $175.0 million, 13.5% on annual global net sales greater than $175.0 million but less than or equal to $500.0 million and 18.5% on annual global net sales greater than $500.0 million. In addition, we purchased the right to receive a payment of $25.0 million, which will be payable upon the achievement of a sales milestone. Lorcaserin is currently in a Phase 3 clinical trial for Dravet syndrome.

Services Agreement

In October 2020, we entered into a services agreement (Services Agreement) with Arena under which Arena agreed to perform certain research and development services, general administrative services, management services and other mutually agreed services for us. The initial term of the Services Agreement was through December 31, 2021, and it then automatically renews for successive one-year terms. Neither party provided notice of non-renewal as of December 31, 2022. Each party may also terminate the Services Agreement for any reason, subject to specified notice periods. During 2022, we significantly reduced our activities under the Services Agreement, including as a result of our having hired employees or contracted with third parties with the requisite expertise, and we are no longer dependent on such services from Arena.

Components of Our Results of Operations

Operating Expenses

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

Research and Development

Our research and development expenses consist primarily of direct and indirect costs incurred in connection with the preclinical and clinical development of our product candidates.

Direct costs include:

- external research and development expenses incurred under agreements with CROs, investigative sites, consultants and other third parties to conduct our preclinical studies and clinical trials; and
- costs related to manufacturing our product candidates for preclinical studies and clinical trials, including fees paid to third-party manufacturers.

Indirect costs include:

- personnel-related costs, which include salaries, payroll taxes, employee benefits, and other employee-related costs, including stock-based compensation, for personnel engaged in research and development functions; and
- other various expenses.

Research and development expenses are recognized as incurred and payments made prior to the receipt of goods or services to be used in research and development are capitalized until the goods or services are received. We track direct costs by stage of program, clinical or preclinical. However, we do not track indirect costs on a program specific or stage of program basis because these costs are deployed across multiple programs and, as such, are not separately classified.

We expect that our research and development expenses will increase substantially for the foreseeable future as we continue the development of our product candidates, particularly as product candidates in later stages of development generally have higher development costs than those in earlier stages of development. We cannot determine with certainty the timing of the initiation, duration or completion costs of future clinical trials and preclinical studies of our product candidates due to the inherently unpredictable nature of clinical and preclinical development. Clinical and preclinical development timelines, the probability of success and development costs can differ materially from expectations.

We anticipate that we will make determinations as to which product candidates and development programs to pursue and how much funding to direct to each product candidate or program on an ongoing basis in response to the results of ongoing and future preclinical studies and clinical trials, regulatory developments and our ongoing assessments as to each product candidate's commercial potential. We will need to raise substantial additional capital in the future. In addition, we cannot forecast which product candidates may be subject to future collaborations, when such arrangements may occur, if at all, and to what degree such arrangements would affect our development plans and capital requirements.

Our research and development expenses may vary significantly based on a variety of factors, such as:

- the scope, rate of progress, expense and results of our preclinical development activities;
- the phase of development of our product candidates;
- per patient clinical trial costs;
- the number of clinical trials required for approval;
- the number of sites included in our ongoing and planned clinical trials;
- the number of patients that participate in our ongoing and planned clinical trials;
- the countries in which our clinical trials are conducted;
- uncertainties in clinical trial design and patient enrollment or drop out or discontinuation rates, particularly in light of the ongoing COVID-19 pandemic and the conflict in Ukraine;
- potential additional safety monitoring requested by regulatory agencies;
- the duration of patient participation in our ongoing and planned clinical trials and follow-up;
- 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 foreign regulatory authorities;
- significant and changing government regulation and regulatory guidance;
- potential additional trials requested by regulatory agencies;
- the cost and timing of manufacturing our product candidates;

- establishing clinical and commercial manufacturing capabilities or making arrangements with third-party manufacturers in order to ensure that we or our third-party manufacturers are able to make product successfully;
- the extent to which we establish additional strategic collaborations or other arrangements;
- the impact of any business interruptions to our operations or to those of the third parties with whom we work, particularly in light of the ongoing COVID-19 pandemic, the conflict in Ukraine and general disruption of global supply chains and financial markets; and
- maintaining a continued acceptable safety profile of our product candidates following approval, if any, of our product candidates.

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

General and Administrative

General and administrative expenses consist primarily of personnel-related costs, which include salaries, payroll taxes, employee benefits, and other employee-related costs, including stock-based compensation, for personnel in executive, finance and other administrative functions. Other significant costs include legal fees relating to corporate matters, professional fees for accounting and consulting services and facility-related costs.

We expect that our ongoing general and administrative expenses will increase modestly for the foreseeable future to support our increased research and development activities and increased costs of operating as a public company and in building our internal resources. These increased costs will include increased expenses related to audit and legal services associated with maintaining compliance with exchange listing and SEC requirements, prosecuting and maintaining our patent portfolio, and investor and public relations activities associated with operating as a public company.

Financial Operations Overview

Results of Operations

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

	Year Ended December 31,	
(in thousands)	**2022**	**2021**
Operating expenses:		
Research and development	$ 34,638	$ 19,774
General and administrative	10,160	8,065
Total operating expenses	44,798	27,839
Loss from operations	(44,798)	(27,839)
Interest income, net	837	64
Other income (expense)	16	(22)
Net loss	$ (43,945)	$ (27,797)

Research and Development Expenses

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

	Year Ended December 31,	
(in thousands)	**2022**	**2021**
Direct costs:		
LP352	$ 19,389	$ 8,212
Preclinical programs	5,596	6,224
Indirect costs:		
Personnel-related	8,408	4,548
All other	1,245	790
Total research and development expenses	$ 34,638	$ 19,774

Research and development expenses were $34.6 million for the year ended December 31, 2022. These expenses include $19.4 million in preclinical and clinical trial expenses related to LP352, $5.6 million in preclinical expenses primarily related to advancing LP659 and $8.4 million in personnel-related expenses. Research and development expenses were $19.8 million for the year ended December 31, 2021. These expenses include $8.2 million in preclinical and clinical trial expenses related to LP352, $6.2 million in preclinical expenses related to advancing LP659 and LP143 and $4.5 million in personnel-related expenses.

General and Administrative Expenses

General and administrative expenses were $10.2 million for the year ended December 31, 2022. These expenses include $5.3 million of personnel-related costs, $2.0 million of professional services and consulting expenses and $1.6 million of insurance expense. General and administrative expenses were $8.1 million for the year ended December 31, 2021. These expenses include $4.0 million of personnel-related costs, $1.7 million of professional services and consulting expenses and $1.5 million of insurance expense.

Liquidity and Capital Resources

Sources of Liquidity

As of December 31, 2022, we had cash, cash equivalents and short-term investments of $67.6 million.

We have funded our operations primarily through the private placement of convertible preferred stock and public issuances and sales of our capital stock.

In October 2020, we completed a $56.0 million private placement of our Series A convertible preferred stock.

In connection with our IPO in March 2021, we issued and sold 5,298,360 shares of common stock, which included 298,360 shares of our common stock issued pursuant to the over-allotment option granted to the underwriters to purchase additional shares of common stock, at a public offering price of $16.00 per share. We raised $76.2 million in net proceeds from the IPO after deducting underwriters' discounts and commissions of $5.9 million and issuance costs of $2.6 million.

In September 2022, we entered into a Controlled Equity Offering℠ Sales Agreement (Sales Agreement) with Cantor Fitzgerald & Co., as sales agent (Cantor Fitzgerald), pursuant to which we may issue and sell our common stock from time to time through our "at the market offering" (ATM) program under the Sales Agreement. We have no obligation to sell any shares of common stock under the Sales Agreement and may at any time suspend sales under the Sales Agreement. Cantor Fitzgerald will be entitled to compensation in an amount of 3% of the gross proceeds of any shares of common stock sold under the Sales Agreement. A maximum of $20.0 million of shares of common stock may be sold under the Sales Agreement. During the year ended December 31, 2022, we sold no shares of our common stock under the Sales Agreement.

In February 2023, we raised $23.0 million in a follow-on public offering. We issued and sold 5,750,000 shares of common stock which included 750,000 shares of our common stock issued pursuant to the over-allotment option granted to the underwriters to purchase additional shares of common stock, at a public offering price of $4.00 per share. We raised $21.2 million in net proceeds from the follow-on public offering after deducting underwriters' commissions of $1.4 million and issuance costs of $0.4 million.

Material Cash Requirements

We have incurred net losses and negative cash flows from operations since our inception and anticipate we will continue to incur net losses for the foreseeable future.

We expect that our existing cash, cash equivalents and short-term investments, including proceeds from the follow-on public offering completed in February 2023, will be sufficient to fund our operations for at least the next 12 months. We believe we will meet longer-term expected future cash requirements and obligations beyond the next 12 months by utilizing our existing cash, cash equivalents and short-term investments and through a combination of equity offerings, debt financings, collaborations, licenses and other similar arrangements. However, our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially. We have based our estimate on assumptions that may prove to be wrong, and we could deplete our capital resources sooner than we expect. Additionally, the process of testing product candidates in clinical trials is costly, and the timing of progress and expenses in these trials is uncertain. Our ability to fund longer-term operating needs will depend on our ability to access the capital markets, our ability to enter into third-party arrangements, and ultimately our ability to commercialize our product candidates for which we may obtain regulatory approval, and other factors, including those discussed in Part II, Item 1A, "Risk Factors" of this Annual Report.

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

- the type, number, scope, progress, expansions, results, costs and timing of, our preclinical studies and clinical trials for our current and any future product candidates and the potential indications which we are pursuing or may choose to pursue in the future;
- the outcome, timing and costs of regulatory review of our product candidates;
- the costs and timing of manufacturing for our product candidates, including commercial manufacturing;
- our efforts to enhance operational systems and hire additional personnel to satisfy our obligations as a public company, including enhanced internal controls over financial reporting;
- the costs associated with hiring additional personnel and consultants as our preclinical and clinical activities increase;
- the terms and timing of establishing and maintaining collaborations, licenses and other similar arrangements;
- the costs of obtaining, expanding, maintaining and enforcing our patent and other intellectual property rights;
- the costs and timing of establishing or securing sales and marketing and distribution capabilities, whether alone or with third parties, to commercialize product candidates for which we may obtain regulatory approval, if any;
- our ability to achieve sufficient market acceptance, coverage and adequate reimbursement from third- party payors and adequate market share and revenue for any approved products;
- patients' willingness to pay out-of-pocket for any approved products in the absence of coverage and/or adequate reimbursement from third-party payors;
- the timing and amount of the payments we are obligated to make under the Arena License Agreement;
- costs associated with any product candidates, products or technologies that we may in-license or acquire; and
- if we experience any delays or encounter any issues with any of the above, which may be exacerbated by macroeconomic events stemming from the ongoing COVID-19 pandemic or evolving geopolitical developments such as the conflict in Ukraine.

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval for any product candidates or generate revenue from the sale of any product candidate for which we may obtain marketing approval. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for at least several years, if ever. As a result, we will need substantial additional financing to support our continuing operations and further the development of and commercialize our product candidates.

Until such time as we can generate significant revenue from sales of our product candidates, if ever, we expect to finance our cash needs through a combination of public or private equity offerings, debt financings or other capital sources, including potential collaborations, licenses and other similar arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our ability to raise additional funds may be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic, the conflict in Ukraine or otherwise. 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 funds through collaborations, or other similar arrangements with third parties, we may have to relinquish valuable rights to our product candidates, future revenue streams or research programs or may have to grant licenses on terms that may not be favorable to us and/or may reduce the value of our common stock. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our research and development programs, future commercialization efforts or other operations, or grant rights to develop and market our product candidates that we would otherwise prefer to develop and market ourselves, which would have a negative impact on our financial condition.

Contractual Obligations

We enter into contracts in the normal course of business with third-party contract organizations for preclinical and clinical studies and testing, manufacture and supply of our preclinical and clinical materials and providing other services and products for operating purposes. These contracts generally provide for termination following a certain period after notice, typically 30 to 60 days, and therefore we believe that our non-cancelable obligations under these agreements are not material.

Cash Flows

The following table sets forth a summary of our cash flows for the years ended December 31, 2022 and 2021:

	Year Ended December 31,	
(in thousands)	**2022**	**2021**
Cash used in operating activities	$ (38,063)	(24,705)
Cash used in investing activities	(17,064)	(40,716)
Cash (used in) provided by financing activities	(444)	76,451
Net (decrease) increase in cash and cash equivalents	$ (55,571)	$ 11,030

Operating Activities

Net cash used in operating activities was $38.1 million and $24.7 million for the years ended December 31, 2022 and 2021, respectively. Net cash used in operating activities during the year ended December 31, 2022 was primarily due to our net loss of $43.9 million, adjusted for $2.7 million of stock-based compensation expense and $3.1 million from changes in operating assets and liabilities. Net cash used in operating activities during the year ended December 31, 2021 was primarily due to our net loss of $27.8 million, adjusted for $2.0 million of stock-based compensation expense and $1.0 million from changes in operating assets and liabilities.

Investing Activities

Net cash used in investing activities was $17.1 million and $40.7 million for the years ended December 31, 2022 and 2021, respectively. Net cash used in investing activities during the year ended December 31, 2022 was related to $57.6 million of short-term investment purchases, which was offset by $40.5 million in short-term investment maturities. Net cash used in investing activities during the year ended December 31, 2021 was related to $40.7 million of short-term investment purchases.

Financing Activities

Net cash (used in) provided by financing activities was $0.4 million and $76.5 million for the years ended December 31, 2022 and 2021, respectively. Net cash used in financing activities during the year ended December 31, 2022 was comprised of financing related expenses. Net cash provided by financing activities during the year ended December 31, 2021 was comprised of net proceeds of $76.5 million from our IPO, which excludes $0.2 million of IPO expenses that were paid in 2020.

Recent Accounting Pronouncements

For detailed information regarding recently issued accounting pronouncements and the expected impact on our financial statements, refer to Note 2 "Summary of Significant Accounting Policies," in the accompanying notes to our audited financial statements included elsewhere in this Annual Report.

Critical Accounting Policies and Estimates

Our financial statements are prepared in accordance with generally accepted accounting principles in the United States. The preparation of our financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, costs and expenses, and the disclosure of contingent assets and liabilities in our financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are 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. We evaluate our estimates and assumptions on a periodic basis. Our actual results may differ from these estimates.

While our significant accounting policies are described in more detail in the notes to our financial statements appearing in this Annual Report, we believe that the following accounting policies are critical to understanding our historical and future performance, as the policies relate to the more significant areas involving management's judgments and estimates used in the preparation of our financial statements.

Accrued Research and Development Expenses

As part of the process of preparing our financial statements, we are required to estimate our accrued research and development expenses as of each balance sheet date. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual costs. The majority of our service providers invoice us in arrears for services performed, based on a pre-determined schedule or when contractual milestones are met, but some require advance payments. 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. If timelines or contracts are modified based upon changes in the protocol or scope of work to be performed, we modify our estimates and accruals accordingly on a prospective basis.

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

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 differences between our estimates of such expenses and the amounts actually incurred.

As of December 31, 2022, a hypothetical 10.0 percent increase in our liability for accrued research and development expenses would have resulted in an increase to our net loss of approximately $0.4 million.

Emerging Growth Company and Smaller Reporting Company Status

We are an "emerging growth company" under the Jumpstart Our Business Startups Act of 2012 (JOBS Act), and as such, we can take advantage of an extended transition period for complying with new or revised accounting standards. This provision allows an emerging growth company to delay the adoption of accounting standards that have different effective dates for public and private companies until those standards would otherwise apply to private companies. We have elected to avail ourselves of this exemption from new or revised accounting standards, and therefore we will not be subject to the same requirements to adopt new or revised accounting standards as other public companies that are not emerging growth companies.

We will cease to be an emerging growth company prior to the end of December 31, 2026 if certain earlier events occur, including if we become a "large accelerated filer" as defined in Rule 12b-2 under the Securities Exchange Act of 1934 (Exchange Act), our annual gross revenues exceed $1.235 billion or we issue more than $1.0 billion of non-convertible debt in any three-year period.

We are also a "smaller reporting company" as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as our voting and non-voting common stock held by non-affiliates is less than $250.0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than $100.0 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

Under SEC rules and regulations, as a smaller reporting company we are not required to provide the information required by this item.

Item 8. Financial Statements and Supplementary Data.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors
Longboard Pharmaceuticals, Inc.:

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Longboard Pharmaceuticals, Inc. (the Company) as of December 31, 2022 and 2021, the related statements of operations and comprehensive loss, convertible preferred stock and stockholders' equity (deficit), and cash flows for each of the years in the two-year period ended December 31, 2022, and the related notes (collectively, 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, 2022 and 2021, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2022, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. 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/ KPMG LLP

We have served as the Company's auditor since 2020.

San Diego, California
March 2, 2023

Longboard Pharmaceuticals, Inc.
Balance Sheets

(in thousands, except share and per share data)	December 31, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 10,775	$ 66,346
Short-term investments	56,814	40,379
Prepaid expenses and other current assets	2,249	1,659
Total current assets	69,838	108,384
Right-of-use assets	736	521
Property and equipment	9	14
Other long-term assets	33	33
Total assets	$ 70,616	$ 108,952
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable	$ 1,310	$ 1,028
Accrued research and development expenses	4,168	2,245
Accrued compensation and related expenses	2,438	1,480
Accrued other expenses	490	352
Right-of-use liabilities, current portion	358	339
Total current liabilities	8,764	5,444
Right-of-use liabilities, net of current portion	382	185
Commitments and contingencies (see Note 9)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; authorized shares - 10,000,000 at December 31, 2022 and 2021, respectively; issued and outstanding shares - none at December 31, 2022 and 2021	—	—
Voting common stock, $0.0001 par value; authorized shares - 300,000,000 at December 31, 2022 and 2021, respectively; issued and outstanding shares - 13,585,950 and 13,440,761 at December 31, 2022 and 2021, respectively, excluding 0 and 145,189 shares, respectively, subject to repurchase	1	1
Non-voting common stock, $0.0001 par value; authorized shares - 10,000,000 at December 31, 2022 and 2021, respectively; issued and outstanding shares - 3,629,400 at December 31, 2022 and 2021, respectively	—	—
Additional paid-in capital	148,303	145,683
Accumulated other comprehensive loss	(692)	(164)
Accumulated deficit	(86,142)	(42,197)
Total stockholders' equity	61,470	103,323
Total liabilities and stockholders' equity	$ 70,616	$ 108,952

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

Longboard Pharmaceuticals, Inc.
Statements of Operations and Comprehensive Loss

(in thousands, except share and per share data)	Year Ended December 31, 2022	2021
Operating expenses:		
Research and development	$ 34,638	$ 19,774
General and administrative	10,160	8,065
Total operating expenses	44,798	27,839
Loss from operations	(44,798)	(27,839)
Interest income, net	837	64
Other income (expense)	16	(22)
Net loss	$ (43,945)	$ (27,797)
Net loss per share, basic and diluted	$ (2.56)	$ (1.93)
Weighted-average shares outstanding, basic and diluted	17,150,907	14,410,502
Comprehensive loss:		
Net loss	$ (43,945)	$ (27,797)
Unrealized loss on short-term investments	(528)	(164)
Comprehensive loss	$ (44,473)	$ (27,961)

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

Longboard Pharmaceuticals, Inc.
Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)

(in thousands, except shares)	Convertible Preferred Stock		Voting Common Stock		Non-Voting Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount				
Balance at December 31, 2020	5,600,000	$ 55,795	3,840,540	$ —	—	$ —	$ 11,708	$ —	$ (14,400)	$ (2,692)
Conversion of Series A convertible preferred stock to common stock in connection with initial public offering	(5,600,000)	(55,795)	4,098,600	—	3,629,400	—	55,794	—	—	55,794
Issuance of common stock in initial public offering, net	—	—	5,298,360	1	—	—	76,214	—	—	76,215
Vesting of restricted stock	—	—	203,261	—	—	—	—	—	—	—
Stock-based compensation	—	—	—	—	—	—	1,967	—	—	1,967
Unrealized loss on short-term investments	—	—	—	—	—	—	—	(164)	—	(164)
Net loss	—	—	—	—	—	—	—	—	(27,797)	(27,797)
Balance at December 31, 2021	—	$ —	13,440,761	$ 1	3,629,400	$ —	$ 145,683	$ (164)	$ (42,197)	$ 103,323
Vesting of restricted stock	—	—	145,189	—	—	—	—	—	—	—
Stock-based compensation	—	—	—	—	—	—	2,657	—	—	2,657
Financing related fees	—	—	—	—	—	—	(37)	—	—	(37)
Unrealized loss on short-term investments	—	—	—	—	—	—	—	(528)	—	(528)
Net loss	—	—	—	—	—	—	—	—	(43,945)	(43,945)
Balance at December 31, 2022	—	$ —	13,585,950	$ 1	3,629,400	$ —	$ 148,303	$ (692)	$ (86,142)	$ 61,470

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

Longboard Pharmaceuticals, Inc.
Statements of Cash Flows

(in thousands)	2022	2021
Cash flows from operating activities:		
Net loss	$ (43,945)	$ (27,797)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	2,657	1,967
Depreciation and amortization	5	1
Accretion of premiums on investments, net	101	157
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(183)	(1,645)
Accounts payable	282	(185)
Accrued research and development expenses	1,923	1,329
Accrued compensation and related expenses	959	1,318
Accrued other expenses	138	146
Operating right-of-use assets and lease liabilities, net	—	4
Net cash used in operating activities	(38,063)	(24,705)
Cash flows from investing activities:		
Purchases of short-term investments	(57,614)	(40,700)
Maturities of short-term investments	40,550	—
Purchase of property and equipment	—	(16)
Net cash used in investing activities	(17,064)	(40,716)
Cash flows from financing activities:		
Series A convertible preferred stock financing costs	—	(1)
Proceeds from initial public offering	—	84,774
Initial public offering costs	—	(8,322)
Financing related fees	(444)	—
Net cash (used in) provided by financing activities	(444)	76,451
Net (decrease) increase in cash and cash equivalents	(55,571)	11,030
Cash and cash equivalents at the beginning of the period	66,346	55,316
Cash and cash equivalents at the end of the period	$ 10,775	$ 66,346
Non-cash investing and financing activities:		
Common stock issued on conversion of convertible preferred stock in connection with initial public offering	$ —	$ 55,794

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

Note 1. Organization and Basis of Presentation

Description of Business

Longboard Pharmaceuticals, Inc. (the Company), formerly Arena Neuroscience, Inc., was incorporated in the state of Delaware on January 3, 2020 and is based in San Diego, California. The Company was organized and initially wholly-owned by Arena Pharmaceuticals, Inc. (Arena), until the closing of its Series A convertible preferred stock (Series A Preferred Stock) financing in October 2020. The Company is a clinical-stage biopharmaceutical company focused on developing novel, transformative medicines for neurological diseases. The Company's most advanced product candidate, LP352, is a serotonin receptor that is being developed for the treatment of seizures associated with developmental and epileptic encephalopathies and is currently in a Phase 1b/2a clinical trial (the PACIFIC Study). The Company is also developing LP659, an S1P receptor modulator, which could have applicability in multiple neurological conditions.

Initial Public Offering

On March 16, 2021, the Company completed the initial public offering (IPO) of its voting common stock. In connection with the IPO, the Company issued and sold 5,298,360 shares of voting common stock, which included 298,360 shares of its voting common stock issued pursuant to the option granted to the underwriters to purchase additional shares in April 2021, at a public offering price of $16.00 per share. The Company raised $76.2 million in net proceeds from the IPO after deducting underwriters' discounts and commissions of $5.9 million and issuance costs of $2.6 million. Unless otherwise noted, all references in the financial statements and related footnotes to the Company's "common stock" refers to the Company's voting common stock.

Immediately prior to the closing of the IPO, 2,630,000 shares of Series A Preferred Stock were exchanged for 3,629,400 shares of non-voting common stock and 2,970,000 shares were automatically converted into 4,098,600 shares of voting common stock. Following the IPO, there were no shares of Series A Preferred Stock outstanding.

Forward Stock Split

On March 5, 2021, the Company filed an amendment to the Company's amended and restated certificate of incorporation to effect a forward stock split of shares of the Company's common stock on a 1.38-for-1 basis (March Forward Stock Split). Adjustments corresponding to the March Forward Stock Split were made to the ratio at which the Company's Series A Preferred Stock were converted into common stock immediately prior to the closing of the IPO. The par value of the common stock and number of shares authorized were not adjusted as a result of the March Forward Stock Split. All references to common stock, options to purchase common stock, share data, per share data, and related information contained in the financial statements and related footnotes have been retrospectively adjusted to reflect the effect of the March Forward Stock Split for all periods presented.

Basis of Presentation

The Company's financial statements have been prepared in accordance with US generally accepted accounting principles (GAAP) and reflect all of the Company's activities. The financial statements include all known adjustments necessary for a fair presentation of the results as required by GAAP. These adjustments consist primarily of normal recurring accruals and estimates that impact the carrying value of assets and liabilities. Operating results for the year ended December 31, 2022, are not necessarily indicative of future results.

Liquidity and Capital Resources

Since its inception, the Company has devoted substantially all of its resources to research and development (R&D) activities, organizing and staffing, business planning, raising capital, in-licensing intellectual property rights and establishing its intellectual property portfolio, and providing general and administrative (G&A) support for these operations and has funded its operations primarily with the net proceeds from the issuance of Series A Preferred Stock and common stock. The Company has incurred losses and negative cash flows from operations since commencement of its operations. The Company had an accumulated deficit of $86.1 million and $42.2 million as of December 31, 2022 and 2021, respectively.

Management expects the Company will incur substantial operating losses for the foreseeable future in order to complete preclinical studies and clinical trials, seek regulatory approval, and launch and commercialize any product candidates for which it receives regulatory approval. The Company will need to raise additional capital through public or private equity or debt financings or other capital sources, including potential collaborations, licenses and other similar arrangements.

Geopolitical and macroeconomic events, such as the COVID-19 pandemic and the conflict in Ukraine, continue to evolve and have resulted in a significant disruption of global financial markets. The Company's ability to raise additional capital may be adversely impacted by potential worsening of global economic conditions and the disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting from such events. If the disruption persists or deepens, the Company could experience an inability to access additional capital.

As of December 31, 2022, the Company had available cash, cash equivalents and investments of $67.6 million and working capital of $61.1 million to fund future operations. Management believes that its capital resources as of December 31, 2022 along with the proceeds from the follow-on public offering completed in February 2023 will be sufficient to fund the Company's operations for at least 12 months after the date these audited financial statements are issued.

Note 2. Summary of Significant Accounting Policies

Use of Estimates

The Company's financial statements are prepared in accordance with GAAP. The preparation of the Company's financial statements requires the Company to make estimates and assumptions that impact the reported amounts of assets, liabilities and expenses and the disclosure of contingent assets and liabilities in the financial statements and accompanying notes. Such estimates include the accrual of R&D expenses and stock-based compensation. Management evaluates its estimates on an ongoing basis. Although estimates are based on the Company's historical experience, knowledge of current events and actions it may undertake in the future, actual results may materially differ from these estimates and assumptions.

Concentration of Credit Risk

Financial instruments which potentially subject the Company to significant concentration of credit risk consist of cash, cash equivalents and short-term investments. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits and invests in short-term investments with the primary objectives of seeking to preserve principal, achieve liquidity requirements and safeguard funds. Management believes that the Company is not exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held and the nature, including the credit-ratings, of its short-term investments.

Segment Reporting

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision-maker in making decisions regarding resource allocation and assessing performance. The Company views its operations and manages its business as one segment.

Cash and Cash Equivalents

The Company considers all highly liquid investments with original maturities of three months or less when purchased to be cash equivalents. Cash and cash equivalents include cash in readily available checking accounts, money market funds, corporate debt securities, and obligations of U.S. Government-sponsored enterprises. The carrying amounts reported in the audited balance sheets for cash and cash equivalents are valued at cost, which approximates fair value.

Short-Term Investments

Short-term investments primarily consist of commercial paper, corporate debt securities, and government and agency bonds. The Company has classified these investments as available-for-sale securities, as the sale of such investments may be required prior to maturity to implement management strategies, and therefore has classified all investments with maturity dates beyond three months at the date of purchase as current assets in the accompanying audited balance sheets. Any premium or discount arising at purchase is amortized and/or accreted to interest income as an adjustment to yield using the straight-line method over the life of the instrument. Investments are reported at their estimated fair value. Unrealized gains and losses are included in accumulated other comprehensive loss as a component of stockholders' equity until realized.

Property and Equipment, Net

Property and equipment are stated at cost and depreciated on a straight-line basis over the estimated useful life of the related assets (generally three to five years). Property and equipment as of December 31, 2022 consists of computer equipment.

R&D Expenses

R&D expenses are expensed in the periods in which they are incurred. External expenses consist primarily of payments to contract research organizations, outside consultants and other third parties in connection with the Company's discovery, preclinical and clinical activities, process development, manufacturing activities, regulatory and other services. Certain R&D external expenses are recognized based on an evaluation of the progress to completion of specific tasks using information provided to the Company by its service providers or the estimate of the level of service that has been performed at each reporting date. R&D expenses amounted to $34.6 million and $19.8 million, respectively, for the years ended December 31, 2022 and 2021.

Stock-Based Compensation

In October 2020, the Company's board of directors and stockholders approved the 2020 Equity Incentive Plan (2020 Plan). The Company's board of directors adopted the 2021 Equity Incentive Plan (2021 Plan) in February 2021 and the Company's stockholders approved the 2021 Plan in March 2021. The 2021 Plan is the successor and continuation of the 2020 Plan. Under both the 2021 and 2020 Plans, awards are measured at fair value and recognized over the requisite service period. Forfeitures are accounted for in the period they occur. The Company estimates the fair value of each stock-based award on the date of grant using the Black-Scholes option pricing model which requires the input of subjective assumptions, including price volatility of the underlying stock, risk-free interest rate, dividend yield, and expected term of the option.

Net Loss Per Share

Basic net loss per 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. Since the Company had a net loss in each of the periods presented, basic and diluted net loss per share of common stock are the same.

The table below provides potentially dilutive securities not included in the calculation of the diluted net loss per share as it would be anti-dilutive:

	Year Ended December 31,	
	2022	**2021**
Options to purchase common stock	2,395,748	1,421,756
Restricted stock awards, issued but unvested	—	145,189
Total	2,395,748	1,566,945

Income Taxes

The Company accounts for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements. Under this method, deferred tax assets and liabilities are determined on the basis of the differences between the financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date.

The Company recognizes net deferred tax assets to the extent that the Company believes these assets are more likely than not to be realized. In making such a determination, management considers all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax-planning strategies and results of recent operations. If management determines that the Company would be able to realize its deferred tax assets in the future in excess of their net recorded amount, management would make an adjustment to the deferred tax asset valuation allowance, which would reduce the provision for income taxes.

The Company records uncertain tax positions on the basis of a two-step process whereby (1) management determines whether it is more likely than not that the tax positions will be sustained on the basis of the technical merits of the position and (2) for those tax positions that meet the more-likely-than-not recognition threshold, management recognizes the largest amount of tax benefit that is more than 50 percent likely to be realized upon ultimate settlement with the related tax authority. The Company recognizes interest

and penalties related to unrecognized tax benefits within income tax expense. Any accrued interest and penalties are included within the related tax liability.

Comprehensive Loss

Comprehensive loss is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources, including unrealized gains and losses on short-term investments.

Recent Accounting Pronouncements

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments - Credit Losses*, to improve financial reporting by requiring timely recording of credit losses on loans and other financial instruments held by financial institutions and other organizations. The ASU requires the measurement of all expected credit losses for financial assets held at the reporting date based on historical experience, current conditions and reasonable and supportable forecasts. This guidance became effective for the Company on January 1, 2023. The Company does not expect the adoption of this standard to have a material impact on its financial statements.

Risks and Uncertainties

In December 2019, COVID-19, a novel strain of coronavirus, was first identified in Wuhan, China. In March 2020, the World Health Organization categorized COVID-19 as a pandemic, and the virus has spread to over 100 countries, including the United States. The impact of this pandemic has been and will likely continue to be extensive in many aspects of society, which has resulted in and will likely continue to result in significant disruptions to the global economy, as well as businesses and capital markets around the world.

Potential impacts to the Company's business include, but are not limited to, temporary closures of facilities of its vendors, disruptions or restrictions on its employees' ability to travel, disruptions to or delays in ongoing laboratory experiments, preclinical studies, clinical trials, third-party manufacturing supply and other operations, the potential diversion of healthcare resources away from the conduct of clinical trials to focus on pandemic concerns, interruptions or delays in the operations of the U.S. Food and Drug Administration or other regulatory authorities, and the Company's ability to raise capital and conduct business development activities.

In February 2022, Russia commenced a military invasion of Ukraine. The ongoing geopolitical turmoil, including continuing military action in the region and sanctions imposed on Russia, have contributed to further disruption, instability and volatility of the financial markets, which may have an adverse impact on the Company's business or ability to access the capital markets in the future.

Note 3. Fair Value Measurements

The accounting guidance defines fair value, establishes a consistent framework for measuring fair value and expands disclosure for each major asset and liability category measured at fair value on either a recurring or nonrecurring basis. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, the accounting guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1 — Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities.

Level 2 — Quoted prices for similar assets and liabilities in active markets, quoted prices in markets that are not active, or inputs which are observable, either directly or indirectly, for substantially the full term of the asset or liability.

Level 3 — Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (i.e. supported by little or no market activity).

The following table summarizes the Company's financial instruments measured at fair value on a recurring basis as of December 31, 2022 and 2021.

		Fair Value Measurements at Reporting Date Using		
(in thousands)	**Total**	**Quoted Prices in Active Markets for Identical Assets (Level 1)**	**Significant Other Observable Inputs (Level 2)**	**Significant Unobservable Inputs (Level 3)**
As of December 31, 2022				
Assets:				
Money market funds	$ 8,784	$ 8,784	$ —	$ —
Commercial paper	$ 19,429	$ —	$ 19,429	$ —
Corporate debt securities	19,737	—	19,737	—
Government and agency securities	18,639	14,759	3,880	—
Total assets measured at fair value	$ 66,589	$ 23,543	$ 43,046	$ —
As of December 31, 2021				
Assets:				
Money market funds	$ 36,014	$ 36,014	$ —	$ —
Commercial paper	$ 13,987	$ —	$ 13,987	$ —
Corporate debt securities	14,017	—	14,017	—
Government and agency securities	12,375	9,559	2,816	—
Total short-term investments	40,379	9,559	30,820	—
Total assets measured at fair value	$ 76,393	$ 45,573	$ 30,820	$ —

The carrying amounts of the Company’s cash equivalents and accounts payable approximate fair value due to their relatively short maturities.

Note 4. Short-Term Investments

The following table summarizes short-term investments (in thousands):

	As of December 31, 2022			
		Unrealized		
(in thousands)	**Amortized Cost**	**Gains**	**Losses**	**Estimated Fair Value**
Commercial paper	$ 18,453	$ —	$ (15)	$ 18,438
Corporate debt securities	20,090	—	(353)	19,737
Government and agency securities	18,963	1	(325)	18,639
Total short-term investments	$ 57,506	$ 1	$ (693)	$ 56,814

	As of December 31, 2021			
		Unrealized		
(in thousands)	**Amortized Cost**	**Gains**	**Losses**	**Estimated Fair Value**
Commercial paper	$ 13,987	$ —	$ —	$ 13,987
Corporate debt securities	14,117	—	(100)	14,017
Government and agency securities	12,439	—	(64)	12,375
Total short-term investments	$ 40,543	$ —	$ (164)	$ 40,379

The following table summarizes the maturities of the Company's short-term investments at December 31, 2022:

(in thousands)	Amortized Cost	Estimated Fair Value
Due in one year or less	$ 49,139	$ 48,834
Due after one year through two years	8,367	7,980
Total short-term investments	$ 57,506	$ 56,814

The following table shows the Company's available-for-sale investments' gross unrealized losses and fair value aggregated by investment category and length of time that individual securities have been in a continuous loss position, at December 31, 2022 and 2021:

	As of December 31, 2022								
	Less than 12 months			More than 12 months			Total		
(in thousands)	Count	Fair Value	Unrealized Losses	Count	Fair Value	Unrealized Losses	Count	Fair Value	Unrealized Losses
Commercial paper	8	$ 7,934	$ (15)	—	$ —	$ —	8	$ 7,934	$ (15)
Corporate debt securities	7	7,626	(43)	9	12,111	(310)	16	19,737	(353)
Government and agency securities	3	4,511	(37)	6	10,653	(288)	9	15,164	(325)
	18	$ 20,071	$ (95)	15	$ 22,764	$ (598)	33	$ 42,835	$ (693)

	As of December 31, 2021								
	Less than 12 months			More than 12 months			Total		
(in thousands)	Count	Fair Value	Unrealized Losses	Count	Fair Value	Unrealized Losses	Count	Fair Value	Unrealized Losses
Commercial paper	—	$ —	$ —	—	$ —	$ —	—	$ —	$ —
Corporate debt securities	10	14,017	(100)	—	—	—	10	14,017	(100)
Government and agency securities	7	12,375	(64)	—	—	—	7	12,375	(64)
	17	$ 26,392	$ (164)	—	$ —	$ —	17	$ 26,392	$ (164)

The Company reviews its investments to identify and evaluate investments that have an indication of possible other-than-temporary impairment. Factors considered in determining whether a loss is other-than-temporary include the length of time and extent to which fair value has been less than the cost basis, any changes to the underlying credit risk of the investment, and the Company's intent and ability to hold the investment for a period of time sufficient to allow for any anticipated recovery in market value. The unrealized losses in the Company's investments were caused by changes in interest rates caused by changing economic conditions, and not from a decline in credit of their underlying issuers. The Company does not generally intend to sell these investments and it is not more likely than not that the Company will be required to sell these investments before recovery of their amortized cost basis which may be at maturity. As such, the Company has classified these losses as temporary in nature.

Note 5. Accrued Other Expenses

Accrued other expenses consisted of the following (in thousands):

	As of December 31,	
	2022	2021
Accrued consulting fees	$ 254	$ 97
Accrued legal and accounting fees	127	7
Accrued taxes	34	168
Accrued computer related expenses	15	27
Accrued recruiting fees	—	30
Accrued other	60	23
Total	$ 490	$ 352

Note 6. Stockholders' Equity

Sales Agreement

In September 2022, the Company entered into a Controlled Equity Offering[SM] Sales Agreement (the Sales Agreement) with Cantor Fitzgerald & Co., as sales agent (Cantor Fitzgerald), pursuant to which it may issue and sell its common stock from time to time through an "at the market offering" (ATM) program under the Sales Agreement. The Company has no obligation to sell any shares of common stock under the Sales Agreement and may at any time suspend sales under the Sales Agreement. Cantor Fitzgerald will be entitled to compensation in an amount of 3% of the gross proceeds of any shares of common stock sold under the Sales Agreement. A maximum of $20.0 million of shares of common stock may be sold under the Sales Agreement. The Company had not sold any shares of its common stock under the Sales Agreement as of December 31, 2022.

Amended and Restated Certificate of Incorporation

In March 2021, the Company amended and restated the Company's certificate of incorporation to, among other things, increase the authorized shares of voting common stock, non-voting common stock and preferred stock to 300,000,000 shares, 10,000,000 shares and 10,000,000 shares, respectively.

Voting Common Stock and Non-Voting Common Stock

As of December 31, 2022, the Company had 13,585,950 shares of voting common stock outstanding and 3,629,400 shares of non-voting common stock outstanding. As of December 31, 2021, the Company had 13,440,761 shares of voting common stock outstanding, excluding 145,189 shares subject to repurchase, and 3,629,400 shares of non-voting common stock outstanding.

Note 7. Agreements with Arena Pharmaceuticals, Inc.

The Company entered into a license agreement (the License Agreement), a services agreement (the Services Agreement), and a royalty purchase agreement (the Royalty Purchase Agreement) in October 2020 with Arena, which was subsequently amended as described below. Arena was purchased by Pfizer in March 2022. The following section summarizes these related party agreements.

License Agreement

Pursuant to the License Agreement, the Company has obtained an exclusive, royalty bearing, sublicensable, worldwide license under certain know-how and patents of Arena to develop and commercialize LP352 for any use in humans, LP143 and certain 5-HT2A compounds for the treatment of any central nervous system (CNS) indication in humans (excluding the treatment, prevention or amelioration of pain or any gastrointestinal, non-CNS autoimmune or cardiovascular disorder), and LP659 for the treatment of selected CNS indications in humans (pharmaceutical products containing any such compounds, Licensed Products). In January 2022, the Company and Arena amended the Arena License Agreement to add additional 5-HT2A compounds, and in September 2022 the Company and Arena further amended the Arena License Agreement to expand the field of the license of LP659 and provide Arena a right of first negotiation to acquire certain development and commercial rights to LP659 products. As consideration for the rights granted to the Company under the License Agreement, the Company will be required to pay to Arena a mid-single digit royalty on net sales of Licensed Products of LP352, and a low-single digit royalty on net sales of all other Licensed Products, by the Company, its affiliates or its sublicensees, subject to standard reductions. The Company's royalty obligations continue on a Licensed Product-by-Licensed Product and country-by-country basis until the later of the (i) tenth anniversary of the first commercial sale of such product in such country or (ii) expiration of the last-to-expire valid claim of the patents licensed by us under the License Agreement covering the manufacture, use or sale of such product in such country.

Services Agreement

In connection with the License Agreement, the Company also entered into a Services Agreement with Arena under which Arena agreed to perform certain research and development services, general administrative services, management services and other mutually agreed services for the Company and receive service fees therefore on an hourly rate based on an annual full time equivalent rate agreed upon by the parties. Arena invoices the Company for services provided on a monthly basis, in arrears. The Services Agreement will continue until December 31, 2022, and will automatically renew for successive one-year terms. Either party may terminate the Services Agreement for any reason, subject to specified notice periods. Payments for services provided under the Services Agreement are recorded to research and development or general and administrative, on the statement of operations, as appropriate. The Company has significantly reduced its activities under the Services Agreement, including as a result of its having

hired employees or contracted with third parties with the requisite expertise, and the Company is no longer substantially dependent on such services from Arena.

The following table summarizes the services expensed under the Services Agreement (in thousands):

	Year Ended December 31,	
	2022	2021
Research and development	$ 93	$ 930
General and administrative	—	94
Total	$ 93	$ 1,024

There were $0 and $188,000 of related party amounts related to the Services Agreement in accounts payable as of December 31, 2022 and 2021, respectively.

Note 8. Stock-Based Compensation

Equity Incentive Plan

In October 2020, the Company's board of directors and stockholder approved the 2020 Plan, which provided for the grant of incentive stock options, nonstatutory stock options, restricted stock awards, restricted stock unit awards, and stock appreciation rights to its employees, members of its board of directors, and consultants. The Company's board of directors determined the exercise price, vesting and expiration period of the grants under the 2020 Plan.

The Company's board of directors adopted the 2021 Plan in February 2021 and the Company's stockholders approved the 2021 Plan in March 2021. The 2021 Plan became effective on March 11, 2021. The 2021 Plan is the successor and continuation of the 2020 Plan. No additional awards may be granted under the 2020 Plan and all outstanding awards under the 2020 Plan remain subject to the terms of the 2020 Plan. As of December 31, 2022, the 2021 Plan authorizes and provides for the issuance of up to 3,694,999 shares of common stock, which amount will be increased to the extent that awards granted under the 2021 Plan are forfeited, expire or are settled for cash (except as otherwise provided in the 2021 Plan). The number of shares of common stock reserved for issuance under the 2021 Plan automatically increases on January 1 of each calendar year, through January 1, 2031, in an amount equal to (i) 5% of the total number of shares of common stock outstanding on December 31 of the fiscal year before the date of each automatic increase (determined on an as-converted to voting common stock basis, without regard to any limitations on the conversion of the non-voting common stock), or (ii) a lesser number of shares determined by the Company's board of directors prior to the applicable January 1. Recipients of stock options are eligible to purchase shares of the Company's common stock at an exercise price equal to no less than the estimated fair market value of such stock on the date of grant. The maximum term of options granted under the 2020 and 2021 Plans (or collectively, Equity Plans) is ten years and, in general, the options issued under the Equity Plans vest over a one to four year period from the vesting commencement date. There are 1,299,251 shares available for grant under the 2021 Plan as of December 31, 2022.

Stock Award Grants under the Equity Plans

A summary of the Company's Equity Plans stock option activity is as follows:

	Number of Options Outstanding	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in Years)	Aggregate Intrinsic Value (in thousands)
Balance at December 31, 2020	873,264	$ 3.42	9.9	$ 174
Options granted	548,492	10.90		
Options exercised	—	—		
Options cancelled	—	—		
Balance at December 31, 2021	1,421,756	$ 6.31	9.1	$ 1,272
Options granted	1,244,802	4.61		
Options exercised	—	—		
Options forfeited/cancelled	(270,810)	5.65		
Balance at December 31, 2022	2,395,748	$ 5.50	8.3	$ 48
Vested and expected to vest at December 31, 2022	2,395,748	$ 5.50	8.3	$ 48
Options exercisable at December 31, 2022	1,055,847	$ 5.25	7.5	$ 48

Options exercisable at December 31, 2022 included 736,434 vested stock options and 319,413 stock options that are subject to an early exercise provision.

The following table presents the weighted-average assumptions used for the stock option grants for the years ended December 31, 2022 and 2021, along with the related grant date fair value:

	2022	2021
Stock price	$ 4.61	$ 10.90
Risk-free interest rate	2.15%	0.92%
Dividend yield	0.00%	0.00%
Expected volatility	75.28%	74.35%
Expected life (years)	6.0	6.0
Estimated grant date fair value per share of award granted	$ 3.07	$ 7.04

Determination of Fair Value of Common Stock. Prior to the IPO, there was no public market for the Company's common stock, and therefore, the estimated fair value of common stock for option grants was determined by the Company's board of directors as of the date of each option grant, with input from management, considering the most recently available third-party valuations of common stock and the board of directors' assessment of additional objective and subjective factors that it believed were relevant and which may have changed from the date of the most recent valuation through the date of the grant. Historically, these third-party valuations of our equity instruments were performed contemporaneously with identified value inflection points. These third-party valuations were performed in accordance with the guidance outlined in the *American Institute of Certified Public Accountants' Accounting and Valuation Guide, Valuation of Privately-Held-Company Equity Securities Issued as Compensation* (Practice Aid). The Practice Aid identifies various available methods for allocating the enterprise value across classes of series of capital stock in determining the fair value of the common stock at each valuation date.

In addition to considering the results of these third-party valuations, the Company's board of directors considered various objective and subjective factors to determine the fair value of its common stock as of each grant date, including: the prices of the preferred stock sold to or exchanged between outside investors in arm's length transactions and the rights, preferences and privileges of the preferred stock as compared to those of the Company's common stock including liquidation preferences of the Company's preferred stock; the progress of the Company's research and development programs, including the status and results of preclinical and clinical trials for product candidates; the stage of development and material risks related to the Company's business; external market and other conditions affecting the biopharmaceutical industry and trends within the biopharmaceutical industry; the Company's business conditions and projections; the Company's financial position and its historical and forecasted performance and operating results; the lack of an active public market for the Company's common stock and preferred stock; the likelihood of achieving a liquidity event for the Company's securityholders, such as an initial public offering or a sale of the Company in light of prevailing market conditions; the hiring of key personnel and the experience of management; and the analysis of initial public offerings and the

market performance of similar companies in the biopharmaceutical industry, as well as trends and developments in the biopharmaceutical industry.

Significant changes to the key assumptions underlying the factors used could result in different fair values of common stock at each valuation date.

After the closing of the IPO in March 2021, the Company began utilizing the closing stock price of the common stock on the Nasdaq Global Market as both the exercise price and an input to the Black Scholes option pricing model to determine stock-based compensation expense.

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 similar to the expected term of the awards.

Expected dividend yield. The Company bases the expected dividend yield assumption on the fact that it has never paid cash dividends and has no present intention to pay cash dividends and, therefore, used an expected dividend yield of zero.

Expected volatility. Since the Company is a newly public company and does not have a trading history for its common stock, the expected volatility assumption is based on volatilities of a peer group of similar companies whose share prices are publicly available. The peer group was developed based on companies in the biotechnology industry. The Company will continue to apply this process until a sufficient amount of historical information regarding the volatility of its own stock price becomes available.

Expected life. The expected life represents the period of time that options are expected to be outstanding. Because the Company does not have historical exercise behavior, it determines the expected life assumption using the simplified method, for employees, which is an average of the contractual term of the option and its vesting period. The expected term for nonemployee options is equal to the contractual term.

Restricted Stock Awards

In October 2020, 348,450 restricted stock awards were granted to an employee under the 2020 Plan, which vest over two years and had an estimated fair value of $3.12 per share at the time of grant. During 2022 and 2021, 145,189 and 203,261 restricted stock awards vested, respectively; the total fair value of the vested awards was $1.1 million. As of December 31, 2022, all restricted stock awards were vested. For the years ended December 31, 2022 and 2021, $0.4 million and $0.5 million of stock-based compensation related to the restricted stock awards was recorded in general and administrative expense, respectively.

Stock-Based Compensation Expense

Stock-based compensation expense recognized for all equity awards has been reported in the statements of operations and comprehensive loss as follows:

	Year Ended December 31,	
(in thousands)	**2022**	**2021**
Research and development	$ 1,016	$ 561
General and administrative	1,641	1,406
Total	$ 2,657	$ 1,967

As of December 31, 2022, unrecognized stock-based compensation expense was $5.0 million, which is expected to be recognized over a remaining weighted-average period of approximately 2.6 years.

Employee Stock Purchase Plan

The Company's board of directors adopted the 2021 Employee Stock Purchase Plan (ESPP) in February 2021, the Company's stockholders approved the ESPP in March 2021 and it became effective on March 11, 2021. The ESPP initially authorizes the issuance of 353,339 shares of common stock under purchase rights granted to the Company's employees. The number of shares of common stock reserved for issuance will automatically increase on January 1 of each calendar year, beginning on January 1, 2022 through January 1, 2031, by the lesser of (i) 1% of the total number of shares of common stock outstanding on the last day of the fiscal year before the date of the automatic increase (determining on an as-converted to voting common stock basis, without regard to any limitations on the conversion of the non-voting common stock); and (ii) such number of shares of common stock that would cause the

aggregate number of shares of common stock then reserved for issuance under the ESPP to equal 1,060,017 shares; provided that before the date of any such increase, the Company's board of directors may determine that such increase will be for a lesser amount of shares. The ESPP permits eligible employees, who elect to participate in an offering under the ESPP, to contribute up to 15% of their eligible earnings (as defined in the ESPP) towards the purchase of shares of common stock. Unless otherwise determined by the Company's board of directors, the price at which stock is purchased under the ESPP is equal will be 85% of the fair market value of the Company's common stock on the commencement date of each offering period or the relevant purchase date, whichever is lower. There are certain service requirements for an employee to be eligible to participate in the ESPP, and no employee may purchase shares under the ESPP at a rate in excess of $25,000 worth of common stock (as determined in accordance with the ESPP). Offering durations under the ESPP may not be longer than 27 months, and the Company may specify shorter purchase periods within each offering. The ESPP is considered a compensatory plan as defined by the authoritative guidance for stock-based compensation. As of December 31, 2022, the ESPP had not yet been implemented.

Note 9. Commitments and Contingencies

Leases

In June 2021, the Company entered into the lease agreement (original lease) for office space located at 4275 Executive Square, Suite 950, La Jolla, California 92037 where it occupies 8,681 square feet. The original lease became effective July 1, 2021, and continues through June 30, 2023. Rent payments were approximately $29,000 per month for the first year and increased by 4.5% in July 2022. A security deposit of $33,000 was paid in June 2021 and is included in other long-term assets on the balance sheet as of December 31, 2022. In August 2022, the Company and the landlord extended the lease agreement (lease extension) through December 31, 2024. Rent payments under the lease extension are approximately $33,000 starting in July 2023 and increase by 4.5% in July 2024.

Previously, the Company leased certain office space in San Diego, California under a month to month lease. Rent payments were approximately $1,000 per month.

Rent expense totaled approximately $394,000 and $198,000 for the years ended December 31, 2022 and 2021, respectively.

The below table provides supplemental cash flow information related to leases as follows (in thousands):

	Year Ended December 31,	
	2022	2021
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$ 370	$ 181
Right-of-use assets obtained in exchange for lease obligations:		
Operating leases	554	679

Supplemental balance sheet information related to leases is as follows (in thousands, except lease term and discount rate):

	December 31,	
	2022	2021
Operating leases		
Right-of-use assets, net	$ 736	$ 521
Right-of-use lease liabilities, current	358	339
Right-of-use lease liabilities, noncurrent	382	185
Total operating lease liabilities	$ 740	$ 524
Weighted average remaining lease term (in years)		
Operating leases	2.0	1.5
Weighted average discount rate		
Operating leases	9.8%	9.0%

Future minimum lease commitments are as follows as of December 31, 2022 (in thousands):

	Operating Leases
Year Ending December 31,	
2023	384
2024	400
Total lease payments	784
Less imputed interest	(44)
Total	$ 740

Contingencies

From time to time, the Company may become subject to claims or suits arising in the ordinary course of business. The Company will accrue a liability for such matters when it is probable that future expenditures will be made and such expenditures can be reasonably estimated. As of December 31, 2022 and 2021, the Company is not a party to any litigation.

Note 10. Income Taxes

The following table summarizes the net loss attributable to stockholders before benefit for income taxes by region for the periods presented:

	Year Ended December 31,	
(in thousands)	**2022**	**2021**
United States	$ (43,945)	$ (27,797)
Total	$ (43,945)	$ (27,797)

The benefit for income taxes are as follows:

	Year Ended December 31,	
(in thousands)	**2022**	**2021**
Benefit for income taxes at statutory federal rate	$ (9,229)	$ (5,855)
Permanent differences and other	524	97
Research and development credits	(1,688)	(679)
Change in valuation allowance	10,393	6,437
Provision for income taxes	$ —	$ —

The components of the Company's net deferred taxes were as follows:

	December 31,	
(in thousands)	**2022**	**2021**
Federal and California net operating loss carryforwards	$ 8,512	$ 6,376
Federal and California research and development carryforwards	2,528	840
Stock-based compensation expense	404	343
Lease liability	155	110
Section 174 capitalized R&D expenses	6,318	—
Other, net	491	301
Total deferred tax assets	18,408	7,970
Right-of-use asset	(155)	(109)
Fixed asset basis difference	(2)	(3)
Total deferred tax liabilities	(157)	(112)
Net deferred tax assets	18,251	7,858
Less: valuation allowance	(18,251)	(7,858)
Net deferred tax assets	$ —	$ —

The deferred income tax assets have been fully offset by a valuation allowance, as realization is dependent on future earnings, if any, the timing and amount of which are uncertain. The net valuation allowance increased by $10.4 million. We will continue to assess the need for a valuation allowance on our deferred tax assets by evaluating both positive and negative evidence that may exist.

As of December 31, 2022, we had federal net operating loss carryforwards of $40.5 million that will not expire and California net operating loss carryforwards of $1.6 million that will begin to expire in 2040. As of December 31, 2022, we also had federal and California research and development tax credit carryforwards, net of reserves, of $1.9 million and $0.8 million respectively. Federal credit carryforwards will begin to expire after 2040 unless previously utilized. The California research and development credit carries forward indefinitely.

Sections 382 and 383 of the IRC limit the utilization of tax attribute carryforwards that arise prior to certain cumulative changes in a corporation's ownership. We have not completed an IRC Section 382/383 analysis regarding the limitation of net operating loss and research and development credit carryforwards.

In accordance with authoritative guidance, the impact of an uncertain income tax position on the income tax return must be recognized at the largest amount that is more-likely-than-not to be sustained upon audit by the relevant taxing authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained.

The following table reconciles the beginning and ending amounts of unrecognized tax benefits for the periods presented:

	Year Ended December 31,	
(in thousands)	**2022**	**2021**
Gross unrecognized tax benefits at the beginning of the year	$ 345	$ 31
Additions from tax positions taken in the current year	359	174
Additions from tax positions taken in prior year	—	140
Reductions from tax positions taken in prior years	(1)	—
Tax settlements	—	—
Gross unrecognized tax benefits at the end of the year	$ 703	$ 345

We had unrecognized tax benefits of $0.7 million as of December 31, 2022. Due to the existence of the valuation allowance, future changes in unrecognized tax benefits will have no impact on our effective tax rate. We do not anticipate that there will be a substantial change in unrecognized tax benefits within the next 12 months. Our practice is to recognize interest and/or penalties related to income tax matters in income tax expense. Because we have incurred net losses since our inception, we did not have any accrued interest or penalties included in our balance sheet as of December 31, 2022 and did not recognize any interest and/or penalties in our statements of operations and comprehensive loss for the year ended December 31, 2022.

We are subject to income taxation in the United States at the Federal and state levels. All tax years are subject to examination by US and California tax authorities due to the carryforward of unutilized net operating losses and tax credits. To our knowledge, we are not currently under examination by any taxing authorities.

Note 11. Employment Benefits

Effective in June 2021, the Company established a 401(k) salary deferral plan for its employees. Employee contributions are voluntary and are determined on an individual basis, limited to the maximum amount allowable under federal tax regulations. The Company provides a safe harbor contribution of up to 4% of the employee's compensation, not to exceed eligible limits, and subject to employee participation. For the years ended December 31, 2022 and 2021, the Company incurred approximately $265,000 and $119,000, respectively, in expenses related to the safe harbor contribution.

Note 12. Subsequent Events

In February 2023, we raised $23.0 million in a follow-on public offering. We issued and sold 5,750,000 shares of common stock which included 750,000 shares of our common stock issued pursuant to the over-allotment option granted to the underwriters to purchase additional shares of common stock, at a public offering price of $4.00 per share. We raised $21.2 million in net proceeds from the follow-on public offering after deducting underwriters' commissions of $1.4 million and issuance costs of $0.4 million.

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

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We maintain "disclosure controls and procedures," as defined in Exchange Act Rules 13a-15(e) and 15d-15(e) that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is (i) recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and (ii) accumulated and communicated to our management, including our principal executive and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applies its judgment in evaluating the cost benefit relationship of possible controls and procedures. Our disclosure controls and procedures are designed to provide reasonable assurance of achieving their control objectives. Our management, with the participation of our principal executive officer and principal financial officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of December 31, 2022, the end of the period covered by this Annual Report. Based upon such evaluation, our principal executive officer and principal financial officer have concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of such date.

Attestation Report of the Registered Public Accounting Firm

This Annual Report on Form 10-K does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting due to an exemption established by the JOBS Act for "emerging growth companies" and because we qualify as a "non-accelerated filer" (i.e., we do not qualify as either an "accelerated filer" or a "large accelerated filer" as defined in Rule 12b-2 under the Exchange Act).

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act). We maintain internal control over financial reporting designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.

Internal control over financial reporting cannot provide absolute assurance of achieving financial reporting objectives because of its inherent limitations. Internal control over financial reporting is a process that involves human diligence and compliance and is subject to lapses in judgment and breakdowns resulting from human failures. Internal control over financial reporting also can be circumvented by collusion or improper management override. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected. Because of such limitations, there is a risk that material misstatements may not be prevented or detected on a timely basis by internal control over financial reporting. However, these inherent limitations are known features of the financial reporting process. Therefore, it is possible to design into the process safeguards to reduce, though not eliminate, this risk.

Under the supervision of and with the participation of our principal executive officer and principal financial officer, our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2022, based on the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in "Internal Control-Integrated Framework" (2013). Based on this assessment, management concluded that our internal control over financial reporting was effective at the reasonable assurance level as of December 31, 2022.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during our fourth fiscal quarter ended December 31, 2022 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this item is incorporated by reference to the information set forth in the sections titled "Information Regarding the Board of Directors and Corporate Governance – Information Regarding Committees of the Board of Directors – Audit Committee," "Information Regarding the Board of Directors and Corporate Governance – Information Regarding Committees of the Board of Directors – Nominating and Corporate Governance Committee," "Election of Directors," "Executive Officers," "Code of Ethics," and "Delinquent Section 16(a) Reports" in our definitive proxy statement for our 2022 Annual Meeting of Stockholders to be filed with the SEC by May 2, 2023, or the Proxy Statement.

We maintain a Code of Business Conduct and Ethics that applies to all our employees, officers and directors. This includes our principal executive officer, principal financial officer and principal accounting officer or controller, or persons performing similar functions. The full text of our Code of Business Conduct and Ethics is posted on our website at www.longboardpharma.com on the "Governance" page of the section titled "Investors." If we make any substantive amendments to the Code of Business Conduct and Ethics or grant any waiver from a provision of the Code of Business Conduct and Ethics to any executive officer or director that are required to be disclosed pursuant to SEC rules, we will promptly disclose the nature of the amendment or waiver on our website or in a current report on Form 8-K. Information contained in, or that can be accessed through, our website is not incorporated by reference herein, and you should not consider information on our website to be part of this Annual Report.

Item 11. Executive Compensation.

The information required by this item is incorporated by reference to the information set forth in the sections titled "Executive Compensation," "Director Compensation" and "Information Regarding the Board of Directors and Corporate Governance – Information Regarding Committees of the Board of Directors – Compensation Committee" in our Proxy Statement.

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

The information required by this item is incorporated by reference to the information set forth in the sections titled "Security Ownership of Certain Beneficial Owners and Management" and "Equity Incentive Plans – Equity Compensation Plan Information" in our Proxy Statement.

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

The information required by this item is incorporated by reference to the information set forth in the sections titled "Information Regarding the Board of Directors and Corporate Governance – Independence of the Board of Directors" and "Transactions with Related Persons and Indemnification" in our Proxy Statement.

Item 14. Principal Accountant Fees and Services.

The information required by this item is incorporated by reference to the information set forth in the sections titled "Principal Accountant Fees and Services" in our Proxy Statement.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(a) The following documents are filed as part of this Annual Report:

(1) Financial Statements. The financial statements filed as part of this Annual Report are included in Part II, Item 8 of this Annual Report.

(2) Financial Statement Schedules. Financial statement schedules have been omitted in this Annual Report because they are not applicable, not required under the instructions, or the information requested is set forth in the financial statements or notes thereto.

(3) Exhibits. The exhibits listed in the accompanying Exhibit Index are filed as part of, or incorporated by reference into, this Annual Report.

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Form 10-Q (File No. 001-40192), filed with the SEC on May 10, 2021).
3.2	Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.2 to the Registrant's Form 10-Q (File No. 001-40192), filed with the SEC on May 10, 2021).
4.1	Form of Common Stock Certificate (incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-253329), filed with the SEC on March 8, 2021).
4.2	Description of Capital Stock (incorporated by reference to Exhibit 4.3 to the Registrant's Form 10-K (File No. 001-40192), filed with the SEC on March 3, 2022).
10.1+	Longboard Pharmaceuticals, Inc. 2020 Equity Incentive Plan (incorporated by reference to Exhibit 10.1 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-253329), filed with the SEC on March 8, 2021).
10.2+	Forms of grant notice, stock option agreement and notice of exercise under the Longboard Pharmaceuticals, Inc. 2020 Equity Incentive Plan (incorporated by reference to Exhibit 10.2 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-253329), filed with the SEC on March 8, 2021).
10.3+	Forms of restricted stock award grant notice and restricted stock award terms and conditions under the Longboard Pharmaceuticals, Inc. 2020 Equity Incentive Plan (incorporated by reference to Exhibit 10.3 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-253329), filed with the SEC on March 8, 2021).
10.4+	Longboard Pharmaceuticals, Inc. 2021 Equity Incentive Plan (incorporated by reference to Exhibit 10.4 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-253329), filed with the SEC on March 8, 2021).
10.5+	Forms of grant notice, stock option agreement and notice of exercise under the Longboard Pharmaceuticals, Inc. 2021 Equity Incentive Plan (incorporated by reference to Exhibit 10.5 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-253329), filed with the SEC on March 8, 2021).
10.6+	Longboard Pharmaceuticals, Inc. 2021 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.6 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-253329), filed with the SEC on March 8, 2021).
10.7+	Longboard Pharmaceuticals, Inc. Performance Bonus Plan (incorporated by reference to Exhibit 10.7 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-253329), filed with the SEC on March 8, 2021).
10.8+	Form of Indemnification Agreement by and between the registrant and each director and executive officer (incorporated by reference to Exhibit 10.8 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-253329), filed with the SEC on March 8, 2021).
10.9+	Non-Employee Director Compensation Policy (incorporated by reference to Exhibit 10.9 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-253329), filed with the SEC on March 8, 2021).
10.10+	Amended and Restated Employment Agreement by and between the Registrant and Kevin R. Lind, dated March 1, 2021 (incorporated by reference to Exhibit 10.10 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-253329), filed with the SEC on March 8, 2021).
10.11+	Amended and Restated Offer Letter by and between the Registrant and Brandi L. Roberts, dated March 1, 2021 (incorporated by reference to Exhibit 10.12 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-253329), filed with the SEC on March 8, 2021).
10.12	License Agreement by and between the Registrant and Arena Pharmaceuticals, Inc., dated October 27, 2020 (incorporated by reference to Exhibit 10.13 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-253329), filed with the SEC on March 8, 2021.
10.13	First Amendment, dated January 28, 2022, to Arena License Agreement (incorporated by reference to Exhibit 10.14 to the Registrant's Form 10-K (File No. 001-40192), filed with the SEC on March 3, 2022).
10.14	Second Amendment, dated September 13, 2022, to Arena License Agreement (incorporated by reference to Exhibit 10.1 to the Registrant's Form 10-Q (File No. 001-40192), filed with the SEC on November 3, 2022).
10.15	Royalty Purchase Agreement by and among the registrant, Arena Pharmaceuticals, Inc. and 356 Royalty Inc., dated October 27, 2020 (incorporated by reference to Exhibit 10.14 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-253329), filed with the SEC on March 8, 2021).
10.16	Controlled Equity Offering℠ Sales Agreement, dated as of September 30, 2022, by and between the Registrant and Cantor Fitzgerald & Co. (incorporated by reference to Exhibit 1.2 to the Registrant's Registration Statement on Form S-3 (File No. 267674), filed with the SEC on September 30, 2022)
10.17+	Employment Agreement by and between the Registrant and Randall E. Kaye, M.D., dated March 17, 2022 (incorporated by reference to Exhibit 10.3 to the Registrant's Form 10-Q (File No. 001-40192), filed with the SEC on May 5, 2022).
23.1*	Consent of Independent Registered Public Accounting Firm.
24.1	Power of Attorney (included on the signature page to this report).

31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as amended, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as amended, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*#	Certification of Principal Executive Officer and Principal Financial Officer Under Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended and 18 U.S.C. Section 1350.
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL 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 (embedded within the Inline XBRL document)

* Filed herewith.

\+ Indicates management contract or compensatory plan.

\# The information in Exhibit 32.1 shall not be deemed "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act or the Exchange Act (including this Annual Report), unless the Registrant specifically incorporates the foregoing information into those documents by reference

Item 16. Form 10-K Summary.

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized**.**

Longboard Pharmaceuticals, Inc.

Date: March 2, 2023

By: */s/ Kevin R. Lind*
Kevin R. Lind
President and Chief Executive Officer
(Principal Executive Officer)

Date: March 2, 2023

By: */s/ Brandi L. Roberts*
Brandi L. Roberts
Chief Financial Officer
(Principal Financial and Accounting Officer)

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Kevin R. Lind and Brandi L. Roberts and each of them, as his or her true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution for him or her and in 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 exhibits thereto and other documents in connection therewith, with the SEC, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, and any of them or their substitute or substitutes, may lawfully do or cause to be done by virtue hereof. Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Name	Title	Date
/s/ Kevin R. Lind **Kevin R. Lind**	President and Chief Executive Officer *(Principal Executive Officer)*	March 2, 2023
/s/ Brandi L. Roberts **Brandi L. Roberts**	Chief Financial Officer *(Principal Financial and Accounting Officer)*	March 2, 2023
/s/ Vincent E. Aurentz **Vincent E. Aurentz**	Director	March 2, 2023
/s/ Corinne Le Goff **Corinne Le Goff, Pharm.D.**	Director	March 2, 2023
/s/ Casey C. Lynch **Casey C. Lynch**	Director	March 2, 2023
/s/ Phillip M. Schneider **Phillip M. Schneider**	Director	March 2, 2023
/s/ Paul J. Sekhri **Paul J. Sekhri**	Director	March 2, 2023
/s/ Jane Tiller **Jane Tiller, MBChB, FRCPsych**	Director	March 2, 2023

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the registration statement on Form S-8 (No. 333-254244) and (No. 333-263272) and on Form S-3 (No. 333-267674) of our report dated March 2, 2023, with respect to the financial statements of Longboard Pharmaceuticals, Inc.

/s/ KPMG LLP

San Diego, California
March 2, 2023

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, Kevin R. Lind, certify that:

- I have reviewed this Annual Report on Form 10-K of Longboard Pharmaceuticals, Inc.;

- 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;

- 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;

- 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    - 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;

    - Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    - 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

    - 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

- 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):

    - 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

    - 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.

Date: March 2, 2023

By: */s/ Kevin R. Lind*

Kevin R. Lind
President and Chief Executive Officer
(Principal 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, Brandi L. Roberts, certify that:

- I have reviewed this Annual Report on Form 10-K of Longboard Pharmaceuticals, Inc.;

- 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;

- 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;

- 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    - 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;

    - Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    - 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

    - 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

- 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):

    - 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

    - 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.

Date: March 2, 2023

By: */s/ Brandi L. Roberts*

Brandi L. Roberts
Chief Financial Officer
(Principal Financial and Accounting 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

In connection with the Annual Report of Longboard Pharmaceuticals, Inc. (the "Company") on Form 10-K for the year ended December 31, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

- The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: March 2, 2023

By: */s/ Kevin R. Lind*
Kevin R. Lind
President and Chief Executive Officer
(Principal Executive Officer)

Date: March 2, 2023

By: */s/ Brandi L. Roberts*
Brandi L. Roberts
Chief Financial Officer
(Principal Financial and Accounting 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 Longboard Pharmaceuticals, 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.