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, 2025

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 001-42831

LB Pharmaceuticals Inc

(Exact name of Registrant as specified in its Charter)

Delaware	**81-1854347**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
One Pennsylvania Plaza, Suite 1025	
New York, NY	**10119**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (212) 605-0300

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, $0.0001 par value	LBRX	The Nasdaq Stock Market LLC

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

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES ☐ NO ☒

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 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 Exchange Act). YES ☐ NO ☒

The registrant was not a public company as of the last business day of its most recently completed second fiscal quarter and therefore cannot calculate the aggregate market value of its voting and non-voting common equity held by non-affiliates as of such date. The registrant's Common Stock began trading on the Nasdaq Global Market on September 11, 2025.

The number of shares of Registrant's Common Stock outstanding as of March 23, 2026 was 28,674,827.

DOCUMENTS INCORPORATED BY REFERENCE

Part III incorporates certain information by reference from the registrant's proxy statement for the 2026 Annual Meeting of Shareholders. Such proxy statement will be filed no later than 120 days after the close of the registrant's fiscal year ended December 31, 2025.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains express or implied forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. These statements are based on our management's belief and assumptions and on information currently available to our management. Although we believe that the expectations reflected in these forward-looking statements are reasonable, these statements relate to future events or our future operational or 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. Forward-looking statements in this Annual Report on Form 10-K include, but are not limited to, statements about:

- the initiation, timing, progress, potential registrational quality, and results of our research and development programs, preclinical studies, any clinical trials, Investigational New Drug, or IND, and other regulatory submissions;
- the ability of our approach to reproducibly predict treatment outcomes for LB-102 amongst identified patient populations and achieve clinical success;
- the timing of and costs involved in obtaining and maintaining regulatory approval of LB-102 and any future product candidates that we may identify or develop;
- the beneficial characteristics, including potential safety, efficacy, and therapeutic effects, of LB-102;
- our ability to efficiently and cost-effectively conduct our current and future clinical trials, including our plan to incorporate improvements to enhance commercial scalability of our drug product manufacturing;
- our ability to obtain funding for our operations necessary to complete further development and commercialization of LB-102, if approved;
- our ability to maintain existing, and establish new, strategic collaborations, licensing, or other arrangements, including our ability to comply with our financial obligations pursuant to the terms of such agreements;
- the timing and likelihood of the achievement of milestones pursuant to our existing collaboration and licensing agreements;
- our ability to identify and develop LB-102 for treatment of additional indications;
- the performance of our third-party service providers, including our suppliers and manufacturers;
- the ability of our third-party manufacturers to increase the scale of its production of our product candidate, and/or increase the product yield of its manufacturing;
- the rate and degree of market acceptance and clinical utility for LB-102 and any other product candidates we may develop;
- the effects of competition with respect to LB-102 or any of our future product candidates, as well as innovations by current and future competitors in our industry;
- our estimates regarding the potential market opportunities and the number of patients for LB-102 and any future product candidates, if approved for commercial use;
- the implementation of our strategic plans for our business, LB-102, and any future product candidates we may develop;
- our intellectual property position, including the scope of protection we are able to establish, maintain, defend and enforce for intellectual property rights covering LB-102 and any future product candidates we may develop;
- our ability to attract and retain key scientific or management personnel;
- regulatory and legal developments in the United States and foreign countries;
- our ability to attract and retain employees and collaborators with development, regulatory, and commercialization expertise;

- the accuracy of our estimates regarding future expenses, future revenue, capital requirements, and need for additional financing;
- the period over which we estimate our existing cash, cash equivalents and marketable securities will be sufficient to fund our future operating expenses and capital expenditure requirements;
- our expectations regarding the period during which we qualify as an emerging growth company under the JOBS Act; and
- other risks and uncertainties, including those listed under the caption "Risk Factors."

In some cases, forward-looking statements can be identified by terminology such as "may," "should," "expects," "intends," "plans," "anticipates," "believes," "estimates," "predicts," "potential," "continue," or the negative of these terms or other comparable terminology. These statements are only predictions. Investors should not place undue reliance on forward-looking statements because they involve known and unknown risks, uncertainties and other factors, which are, in some cases, beyond our control and which could materially affect results. Factors that may cause actual results to differ materially from those implied or projected by forward-looking statements include, among other things, those listed under the section titled "Risk Factors" and elsewhere in this Annual Report on Form 10-K. If one or more of these risks or uncertainties occur, or if our underlying assumptions prove to be incorrect, actual events or results may vary significantly from those implied or projected by the forward-looking statements. No forward-looking statement is a guarantee of future performance. Investors should read this Annual Report on Form 10-K, the documents that we reference in this Annual Report on Form 10-K and the other documents that we file with the Securities and Exchange Commission, or SEC, with the understanding that our actual future results may be materially different from any future results expressed or implied by these forward-looking statements.

While we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. Investors should therefore not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Annual Report on Form 10-K.

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Annual Report on Form 10-K, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

SPECIAL NOTE REGARDING COMPANY REFERENCES

Throughout this Annual Report on Form 10-K, the "Company," "we," "us" and "our" refer to LB Pharmaceuticals Inc.

SPECIAL NOTE REGARDING TRADEMARKS

All trademarks, trade names and service marks appearing in this Annual Report on Form 10-K are the property of their respective owners.

PART I

Item 1. Business.

Overview

We are a late-stage biopharmaceutical company developing novel therapies for the treatment of a wide range of neuropsychiatric disorders including schizophrenia, bipolar depression, adjunctive treatment of major depressive disorder and other diseases. We are building a pipeline that leverages the broad therapeutic potential of our lead product candidate, LB-102, which we believe has the potential to be the first benzamide antipsychotic drug approved for neuropsychiatric disorders in the United States. LB-102 is currently in late-stage clinical development for schizophrenia and bipolar depression. We are also planning to conduct a Phase 2 clinical trial evaluating LB-102 as an adjunctive treatment in major depressive disorder, or MDD. LB-102 is a new chemical entity and a methylated derivative of amisulpride, a second-generation antipsychotic drug approved in over 50 countries, not including the United States, because the development and regulatory requirements of the U.S. Food and Drug Administration, or FDA, for amisulpride were incompatible with patent coverage on the drug. Amisulpride is a generic drug that has been extensively used in clinical practice following its initial approval in France in the 1980s, generating at least two million monthly prescriptions in 2023 in a subset of 16 continental European countries. Among these European prescriptions for amisulpride, our data suggest that approximately 60% are for schizophrenia and schizoaffective disorders, approximately 20% are for mood disorders, approximately 14% are for anxiety, and the remainder are for a variety of other indications.

We designed LB-102 to address the limitations of amisulpride with the aim to create a product candidate with the potential for a differentiated therapeutic profile and strong intellectual property protection. We believe LB-102's mechanism of action, data from our recently completed Phase 2 trial (NOVA-1) of LB-102 in acute schizophrenia, and the heritage of clinical experience with amisulpride support the continued development of LB-102 in both psychosis and mood disorders. In the future, additional expansion opportunities for LB-102 may include predominantly negative symptoms of schizophrenia, Alzheimer's disease psychosis and agitation, as well as other neuropsychiatric diseases. We believe that LB-102, if approved, can become a mainstay of psychiatric practice by offering a potentially attractive alternative to branded and generic therapeutics for the treatment of schizophrenia, bipolar depression, adjunctive MDD and other neuropsychiatric diseases, given the compelling balance of clinical activity and tolerability observed to date.

The U.S. market for branded antipsychotic drugs was approximately $12 billion as of 2024. Antipsychotics that have expanded beyond schizophrenia and into mood disorder indications have realized substantial increases in revenue. Despite the widespread use of generic antipsychotic drugs, several of these branded drugs each generate U.S. sales in excess of $1 billion annually. Additionally, while available therapeutics to treat schizophrenia, bipolar depression, and MDD demonstrate clinical benefit, a significant unmet need remains for a treatment that delivers a more favorable risk–benefit profile by balancing tolerability with rapid onset and sustained, clinically meaningful efficacy with once-daily dosing. This includes addressing persistent residual symptoms—across both psychosis and mood disorders—that continue to impair functioning despite available therapies, underscoring the opportunity for improvement in the management of these conditions.

Our current pipeline is summarized below:

* Subject to positive Phase 3 data.

Our Strategy

Our strategy is to develop LB-102 for the treatment of schizophrenia and mood disorders initially and subsequently for other neuropsychiatric disorders in the United States and internationally. Key elements of our strategy include:

- **Achieve regulatory approval for LB-102 for the treatment of schizophrenia**. The regulatory pathway for antipsychotic drug development in schizophrenia is well-established and provides precedent for regulatory approval requirements. Based on recent positive feedback from the FDA, our current strategy is to utilize our recently completed Phase 2 trial in acute schizophrenia as one of two adequate and well-controlled trials required for FDA approval. In this Phase 2 trial, treatment with LB-102 resulted in a statistically significant decrease in symptoms related to schizophrenia as measured by the change in total PANSS score after four weeks of treatment in all doses of LB-102 evaluated in the trial and demonstrated potential for a class leading tolerability profile among D2 antagonists and partial agonists. In this trial, treatment with LB-102 also resulted in significant improvements in negative symptoms as well as cognitive performance. These results have informed the design of our Phase 3 trial, which we initiated in March of 2026, as well as our planned open label extension trial which we expect to initiate in the second quarter of 2026.

- **Advance LB-102 as a potential multidimensional treatment for patients with schizophrenia.** We believe LB-102 has the potential to treat a broad range of patients living with schizophrenia by addressing positive, negative, and cognitive symptom domains of the disease. In parallel with our ongoing Phase 3 trial and planned open-label extension trial for LB-102, we plan to further evaluate our clinical development strategy for other unmet needs within schizophrenia, including the potential treatment of predominantly negative symptoms of the disease as well as cognitive impairment associated with schizophrenia. 80% of people with schizophrenia have cognitive impairment of some kind, and up to 60% may experience predominantly, clinically relevant negative symptoms that require treatment. There are no approved treatments for these symptom domains of schizophrenia in the United States. Based on our own clinical results and the breadth of third-party data, we believe LB-102 has the potential to become a widely used treatment for schizophrenia.

- **Expand development of LB-102 into bipolar depression, adjunctive MDD and other neuropsychiatric disorders**. Based on the extensive body of third-party research that has been conducted on amisulpride and a non-racemic form of the drug as well as our data with LB-102 in schizophrenia, we believe there is significant opportunity in the clinical development and commercial potential of LB-102 in mood disorders and other psychosis-related indications. We are therefore leveraging our expertise in neuropsychiatry and the unique mechanism of action of LB-102 for further development in bipolar depression and adjunctive MDD. We believe the mechanism of LB-102, preclinical and clinical data for amisulpride and a non-racemic version of amisulpride, as well as our Phase 2 clinical trial results of LB-102 in acute schizophrenia, support development of LB-102 in bipolar depression and adjunctive MDD. We believe these data also support the potential of LB-102 to benefit people living with other neuropsychiatric diseases such as predominantly negative symptoms of schizophrenia and Alzheimer's disease psychosis and agitation. We continue to assess other mood disorders and neuropsychiatric diseases for potential future development.

- **Extend the life-cycle and global reach of LB-102 by advancing alternate formulations**. We are investigating alternate long-acting injectable, or LAI, formulations of LB-102. We believe that such formulations have the potential to provide improved clinical results and treatment adherence for patients compared to oral formulations, for which compliance may be lower. We believe that the success of the 50 mg dose in our schizophrenia Phase 2 trial affords the opportunity to develop an LAI. Additionally, we believe that an LAI formulation of LB-102, if approved, could have additional advantages, including extending the commercial protection for LB-102, potentially providing a better alternative to the currently limited option set of approved LAI antipsychotic drugs for other neuropsychiatric disorders, such as bipolar disorder, and potentially enhancing LB-102's competitive positioning outside of the United States.

- **Maximize the commercial opportunity of LB-102**. We currently own global rights to LB-102 and intend to retain commercialization rights in the United States. If approved for schizophrenia, we expect to commercialize the oral formulation of LB-102 in jurisdictions where amisulpride is unavailable as a generic, and we expect to commercialize an LAI form of LB-102 worldwide. If approved for bipolar depression, we expect to commercialize both the oral and LAI forms of LB-102 worldwide. If approved for adjunctive MDD, we expect to commercialize the oral form of LB-102 worldwide. We expect to expand our team and develop internal resources to support the potential commercialization of LB-102. Additionally, we may

opportunistically evaluate potential commercial collaborations outside of the United States to maximize the value of LB-102.

Our Pipeline Programs

LB-102: An Investigational Antipsychotic—and Potentially the First Benzamide Approved for Schizophrenia in the United States

Schizophrenia

Our lead product candidate, LB‑102, is a Phase 3 oral small molecule in development for the treatment of schizophrenia. LB-102 is designed to address the multidimensional symptom domains of schizophrenia — positive, negative, and cognitive — and has the potential to be the first benzamide approved for neuropsychiatric disorders in the United States. Our ongoing Phase 3 trial (NOVA-2) is enrolling individuals with acute schizophrenia, defined as a sudden and severe worsening of psychotic symptoms such as hallucinations, delusions, and other positive symptoms. Schizophrenia is a chronic, severe, complex, and debilitating psychiatric disorder that affects approximately 1% of the U.S. population and is a leading cause of disability. Symptoms are divided into three categories: (i) psychotic or positive symptoms, which include delusions, hallucinations, and thought disorder; (ii) negative symptoms, which include lack of motivation, interest, or enjoyment in daily activities, withdrawal from social life, and difficulty showing emotions; and (iii) cognitive symptoms, which encompass problems with attention, concentration, and memory. The disease is associated with increased mortality, with approximately 5% of schizophrenia patients dying by suicide, and average overall life expectancy decreasing by as much as 29 years compared to the general population. There is currently no cure for schizophrenia, which means the disease must be managed with life-long therapy, increasing the importance of therapies that have a good balance of safety and efficacy as well as dosing ease which can improve compliance rates.

In January 2025, we announced positive data from our four-week placebo-controlled, double-blinded, Phase 2 trial in the United States, which assessed the safety and efficacy of LB-102 in patients with acute schizophrenia. Results from the trial demonstrated (i) statistically significant clinical activity at all LB-102 doses tested with sustained significant benefit versus placebo as early as the first week after starting treatment; (ii) a compelling average change in overall symptoms (effect size); (iii) a potentially class-leading tolerability profile among D_2/D_3 antagonists and partial agonists; and (iv) a potentially differentiated impact on cognitive performance as measured by the CogState Computerized Schizophrenia Battery of Tests. The trial achieved its primary endpoint of change in the Positive and Negative Syndrome Scale, or PANSS, a 30-item scale that measures the severity of schizophrenia symptoms, from baseline to Week 4. The change in PANSS score has been used as the primary endpoint in registrational trials of antipsychotic drugs, as it provides a comparative measure against baseline; a higher change from baseline can suggest greater improvement in patient symptoms. A statistically significant decrease in symptoms was observed for all three dose cohorts (50 mg, 75 mg, and 100 mg) compared to placebo. Additionally, our Phase 2 trial data showed a statistically significant impact on negative symptoms versus placebo at the 50 mg dose even though the inclusion criteria enriched for patients experiencing predominantly positive symptoms of schizophrenia. An exploratory post-hoc analysis of our Phase 2 data on the treatment effect in patients with negative symptoms at baseline (i.e., those patients with a PANSS Negative Subscore greater than or equal to 24) yielded similar results with a statistically significant impact on negative symptoms versus placebo at the 50 mg dose. LB-102 was generally well tolerated in the clinical trial, with adverse events being mostly transient and mild to moderate in severity. If replicated in our Phase 3 trial, we believe this tolerability profile characterized by low rates of extrapyramidal symptoms, or EPS (including akathisia), minimal sedation, few gastrointestinal side effects, and no orthostasis has the potential to be class-leading among D_2/D_3 antagonists and partial agonists. EPS (including akathisia) comprises a group of movement disorders including involuntary movements, muscle stiffness, and tremors, that, together with sedation, can be burdensome to patients and can result in discontinuation of treatments. The impact of LB-102 on cognitive performance was also evaluated as an exploratory endpoint in this trial. After four weeks of treatment with LB-102, a robust, dose-dependent, and significant treatment effect size was identified in a post-hoc analysis in the completer population for all doses of LB-102 compared with placebo.

We designed our Phase 2 acute schizophrenia trial to be potentially registrational by including a large sample size (n=359), robust statistical analyses, as well as numerous sensitivity analyses. Based on positive end-of-Phase 2 feedback from the FDA, as well as historical precedent, we believe that our Phase 2 acute schizophrenia trial may serve as one of two pivotal trials required for approval of a new drug application, or NDA, in the United States. As a result, we believe there is a viable path to approval of LB-102 in the United States for the treatment of schizophrenia with a single, six-

week Phase 3 trial alongside other NDA-enabling studies. However, there is no guarantee that our Phase 2 trial will serve as one of the two pivotal trials required for FDA approval, and in such case, we may be required to conduct an additional pivotal trial in acute schizophrenia. The adequacy of our Phase 2 trial to support registration will be a matter of review by the FDA at the time of NDA submission and will depend on the totality of the data included in our submission, including the results of our planned Phase 3 trial.

We initiated a six-week Phase 3 trial of LB-102 in patients with schizophrenia in March 2026. Our Phase 3 trial is designed to be a three-arm, inpatient, double-blinded, placebo-controlled, oral once-daily dose of LB-102 in patients with schizophrenia experiencing an acute worsening of psychotic symptoms, with a six-week treatment duration. We are evaluating the effects of 50 mg LB-102 or 100 mg LB-102 versus placebo in this trial, and patients are being randomized in a 1:1:1 ratio across the three arms of the trial. The sample size is expected to be approximately 460 patients, and we are conducting this trial at approximately 25 sites in the United States. The primary endpoint of the trial is change from baseline in PANSS total score at Day 42. We expect to report topline data from this Phase 3 trial in the second half of 2027 and, if positive, meet with the FDA to discuss the potential for submission of an NDA.

Mood Disorders

In addition to our clinical development program in schizophrenia, we plan to leverage our expertise in neuropsychiatry and the unique mechanism of action of LB-102 to develop our product candidate in other indications, starting with bipolar depression and adjunctive treatment of MDD.

Most people living with bipolar depression experience dramatic shifts in mood, energy, and behavior, alternating between manic and depressive states. It is estimated that approximately 40 million people live with bipolar disorder worldwide and 2.8%, or approximately seven million Americans, experience bipolar disorder in a year. Our initial Phase 2 trial in bipolar 1 depression will explore the utility of LB-102 in controlling the depressive symptoms of the disease. We initiated this potentially registrational Phase 2 trial in bipolar 1 depression in January 2026 and expect to report topline data in the first quarter of 2028.

MDD is characterized by persistent depressed mood and loss of interest. It can significantly impair how individuals feel, think, and behave, with substantial impacts on daily functioning and quality of life. It is a common and serious mood disorder and the leading cause of disability worldwide, impacting 280 million people globally and approximately 20 million people in the United States. While some patients achieve an initial or adequate response with currently available therapies, a large proportion experience clinically meaningful residual symptoms and tolerability limitations. For patients with inadequate response to therapy, a second medication is frequently added to the existing medication regimen, often targeting complementary neurochemical pathways with a goal of achieving broader and more durable symptom control. We are planning a Phase 2 trial that will evaluate LB-102 as an adjunctive therapy in MDD. We plan to initiate this trial in early 2027 and expect to report topline data in the first half of 2029.

We believe LB-102's strong and selective antagonism of the D2, D3, and 5HT7 receptors makes it well suited for treating bipolar depression, providing potential control of psychosis and mania through its effects on D2 and potential for antidepressive and pro-cognitive effects through its antagonism of 5HT7 and D3. This receptor binding profile also supports the development of LB-102 as a potential treatment for adjunctive MDD. Moreover, at low doses, LB-102 and amisulpride have selectivity for pre-synaptic autoreceptors that serves to increase dopamine signaling which is underactive in depression. We believe this mechanistic profile supports the potential for efficacy for both depressive and residual symptoms such as anhedonia and cognitive impairment, which remain key unmet needs in the treatment of both bipolar depression and MDD.

Our Phase 2 trial of LB-102 in acute schizophrenia demonstrated strong antipsychotic activity and also suggests opportunities for potential differentiation in bipolar depression and adjunctive MDD given the observed tolerability profile which is characterized by low rates of EPS (including akathisia), minimal sedation, few gastrointestinal side effects, and lack of orthostasis as well as the positive impacts on negative symptoms and cognitive performance observed in the trial. Amisulpride is approved for the treatment of dysthymia, a form of persistent depression, in certain countries outside of the United States and has been shown to be as effective as certain approved agents for MDD and dysthymia. We believe that results in dysthymia and MDD provide strong scientific and clinical rationale for development of LB-102 in the treatment of mood disorders including depressive episodes associated with bipolar disorder or bipolar depression and adjunctive MDD because episodes of major depression, whether unipolar (as in MDD) or bipolar (as in bipolar depression), are typically characterized by a similar imbalance in the neurotransmitters serotonin, noradrenaline,

and dopamine, regardless of the underlying pathophysiology of the disease. There is wide use of amisulpride in mood disorders with approximately 20% of at least two million monthly prescriptions per year in a select group of European countries including Germany, France, Italy, Spain, and several others written for mood disorders. Among these approximately two million prescriptions approximately 3.4% were written for bipolar disorder and approximately16.2% were written for depression. A non-racemic form of amisulpride also showed antidepressant activity in two independent third-party, placebo-controlled bipolar depression trials with an approximately 17- to 18-point reduction in Montgomery–Åsberg Depression Rating Scale, or MADRS, from baseline observed across these studies. Our Phase 2 trial for bipolar depression and our planned Phase 2 trial in adjunctive MDD are designed to compare a fixed-flexible dose of LB-102 versus placebo. This trial design allows us to evaluate two doses of LB-102 in one arm of the trial, thereby increasing the chances for a patient to derive clinical benefit from treatment with LB-102, while retaining the advantages of a two-arm trial, which is known to mitigate the risk of a high placebo rate. Additionally, flexible dose trials typically have better signal detection than fixed dose trials for depression, as flexible dose trials lower the magnitude of symptom reduction with placebo. We believe LB-102 has the potential to provide improved tolerability and clinical activity in bipolar depression and adjunctive MDD compared to currently available treatments worldwide, which are associated with troubling adverse events and insufficient efficacy for certain symptoms, including anhedonia and cognitive deficits associated with these diseases.

LAI Formulation

We are also developing a long-acting injectable, or LAI, formulation of LB-102, which may improve compliance, a common issue in patients with schizophrenia and bipolar disorder. We believe an effective LAI form of LB-102 has the potential to benefit patients worldwide, as relatively few approved agents are available as long-acting formulations and there are no benzamide class LAIs currently available or in development worldwide. The American Psychiatric Association recommends injectable formulations in circumstances where doing so will improve adherence, decrease mortality, reduce hospitalization risk, and decrease treatment discontinuation rates. We have commenced LAI formulation development and expect to continue these efforts in 2026.

LB-102 Background: Leveraging a Proven Mechanism with Third-Party Efficacious Data to Bolster Development for a Broad Range of Indications

LB-102 is a novel, patent-protected benzamide antipsychotic drug that we designed to improve upon the clinical profile of amisulpride and address its limitations. Amisulpride is one of the most effective and commonly used antipsychotic drugs currently approved outside the United States. Amisulpride was ranked as the second most effective antipsychotic drug, after clozapine, in the 2019 Lancet meta-analysis of clinical trials on antipsychotic drugs. In this meta-analysis, amisulpride was ranked the most effective antipsychotic drug in treating positive symptoms and the third most effective in addressing negative symptoms of schizophrenia. Despite amisulpride's efficacy and tolerability profile, it has not received regulatory approval in the United States for the treatment of any neuropsychiatric disorders, including schizophrenia, because the development and regulatory requirements of the FDA were incompatible with patent coverage on the drug.

The methylation we incorporated into LB-102 was designed to improve the tolerability and efficacy profile of amisulpride by addressing its shortcomings, such as limited blood-brain barrier, or BBB, permeability and dosing frequency. Enhanced BBB permeability was expected to improve the potency of the molecule with respect to dopamine receptor binding and enable the use of lower doses compared with amisulpride. The use of lower doses was hypothesized to improve the tolerability profile. We also aimed to create a new chemical entity with strong composition of matter intellectual property protection. We believe that LB-102 addresses these design goals, and we aimed to demonstrate in our clinical trials that LB-102's improved BBB penetration would confer benefits over amisulpride and other antipsychotic drugs, including lower dosing levels, a wider therapeutic window, improved tolerability, and once-daily dosing. Use of lower doses may also improve the feasibility of developing an LAI formulation. We also designed LB-102 to retain the distinct CNS receptor binding profile of amisulpride which we believe underlies its favorable clinical profile compared with other antipsychotics.

We conducted preclinical head-to-head studies with amisulpride to assess whether the clinical development path of amisulpride may provide a risk-mitigated path for our development of LB-102. These studies compared amisulpride to LB-102 in animal models of schizophrenia demonstrated that LB-102 had equivalent or better results than similar doses of amisulpride and that LB-102 bound similarly to the dopamine D2 and D3 receptors, with a Ki (inhibition constant) of 0.82 nM compared to amisulpride's reported Ki of 1.1 nM, and had a similar affinity for the 5-HT7 receptor with a Ki of

31 nM compared to amisulpride's reported Ki of 44 nM. Our Phase 1 trials in healthy volunteers showed that LB-102 was generally well-tolerated, and in our Phase 1b imaging trial, we observed that LB-102 achieved a level of dopamine receptor occupancy in the brain of approximately 70% (50 mg dose) and approximately 80% (100 mg dose) under steady-state conditions; typically, 60% to 80% dopamine receptor occupancy is the target range for efficacy in treating schizophrenia. The dopamine receptor occupancy levels seen in the imaging trial at 50 mg of LB-102 are approximately equivalent to those observed with 300 to 400 mg of amisulpride. By dosing LB-102 at a lower level, we are aiming to decrease side effects common to amisulpride and other antipsychotic drugs currently used to treat schizophrenia. We believe that fewer side effects of a drug may lead to stronger adherence, continued use of the drug, and therefore, better efficacy results and long-term control of the disease. Because each relapse of psychotic symptoms can result in a functional deterioration from which the patient does not fully recover, long-term control of the disease is a key treatment goal.

While our ongoing Phase 3 trial is designed to investigate LB-102 as a treatment for people experiencing the acute phase, or positive symptoms, of schizophrenia, we believe LB-102 also has potential to address predominantly negative symptoms, an indication with significantly fewer treatment options as well as Cognitive Impairment Associated with Schizophrenia, or CIAS, an indication for which there are no approved therapies. We believe that our data with LB-102 as well as data previously generated with amisulpride support the further investigation of LB-102 in these settings and that, if positive, such data have the potential to further differentiate LB-102 from other drugs available for schizophrenia. Amisulpride demonstrated a statistically significant benefit versus placebo in three independent third-party placebo-controlled trials in patients with predominantly negative symptoms with treatment durations ranging from six weeks to six months. Additionally, our Phase 2 trial data showed a statistically significant impact on negative symptoms versus placebo at the 50 mg dose even though the inclusion criteria enriched for patients experiencing predominantly positive symptoms of schizophrenia. An exploratory post-hoc analysis of our Phase 2 data on the treatment effect in patients with negative symptoms at baseline (i.e., those patients with a PANSS Negative Subscore greater than or equal to 24) yielded similar results with a statistically significant impact on negative symptoms versus placebo at the 50 mg dose.

We find these results highly encouraging and plan to explore options to advance LB-102 in this indication. For example, we have developed a synopsis for a Phase 2 trial in patients with predominantly negative symptoms of schizophrenia and expect to seek regulatory guidance on the design of this trial in 2026 to establish a clinical registration path in this setting. We also expect to generate additional negative symptoms data in our ongoing Phase 3 trial and our open label extension trial. Given the robust, dose dependent effects on cognitive performance that we observed in our Phase 2 trial, we also plan to further explore the impact of LB-102 on cognitive performance in patients with schizophrenia both clinically and pre-clinically. For example, concurrently with our Phase 3 trial in patients with acute schizophrenia, we expect to initiate an open label trial in patients with stable schizophrenia that will enroll both patients who participated in the Phase 3 trial as well as patients who did not. Although the primary objective of this trial is to collect the requisite safety data required for an NDA submission, we also expect to collect efficacy data in certain subsets of patients enrolled in this trial. Efficacy measures will include periodic assessments of cognitive performance as well as open label assessments of improvements in positive and negative symptoms, including in patients with prominent negative symptoms at enrollment in the trial. Although we do not expect data from this open label trial to lead to product label claims without additional randomized clinical trials, we believe these data have the potential to further support the differentiation of LB-102 and expect these data to provide publishable valuable insights as we consider further investigating LB-102 as a potential treatment for CIAS as well as in patients with predominantly negative symptoms of schizophrenia or treatment-resistant schizophrenia. Following the potential approval for the treatment of schizophrenia, we may also consider conducting another Phase 3 trial in schizophrenia where LB-102 is used as an adjunctive therapy.

Development of LB-102: Improving Upon Amisulpride

Amisulpride Overview

Amisulpride is a dopamine receptor antagonist originally developed in France in the 1980s and is approved in more than 50 countries worldwide (not including the United States) for the treatment of schizophrenia and, in certain countries outside of the United States, for the treatment of dysthymia, a form of depression, and predominantly negative symptoms of schizophrenia. In 2000, Sanofi S.A., the manufacturer of Solian, the branded version of amisulpride, announced it would not pursue approval for schizophrenia in the United States because the development and regulatory requirements of the FDA were incompatible with its patent coverage on the drug.

Amisulpride in Treating Schizophrenia

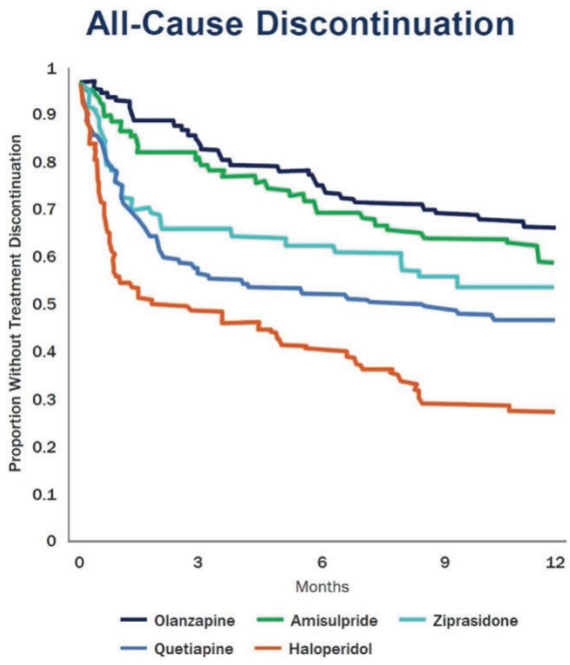
In multiple third-party studies comparing multiple components of clinical efficacy of antipsychotic drugs on schizophrenia, amisulpride consistently scored at or near the top. For example, a 2019 Lancet meta-analysis of clinical trials, which included over 54,000 subjects and 32 medications, found that amisulpride had the highest efficacy as measured by effect on positive symptoms and was second only to clozapine at reducing overall symptoms of schizophrenia. This analysis also found that amisulpride was 20% more effective at reducing overall symptoms of schizophrenia compared to risperidone, which is a first-line treatment for schizophrenia in the United States. A 2020 Lancet Psychiatry report of a head-to-head long-term study showed amisulpride to have greater reduction in PANSS total score from baseline compared to first-line treatments of aripiprazole and olanzapine. In addition, a 2018 systematic review and meta-analysis across 21 randomized, controlled third-party trials showed that in their analysis across these trials, amisulpride was the only antipsychotic drug that outperformed placebo in the treatment of patients who suffer from predominantly negative symptoms.

In 2024, Cobenfy was approved for use in schizophrenia. A 2025 third-party study in European Neuropsychopharmacology highlighted that its overall treatment effect on symptoms was 0.56 using an approach similar to that which was used in the 2019 Lancet meta-analysis. In the table below, we have included the treatment effect of Cobenfy together with those antipsychotic drugs reviewed in the 2019 Lancet meta-analysis for comparison purposes. This table shows how amisulpride's effect size compares with Cobenfy's and the other approved schizophrenia drugs.

Drug	Effect size (Overall change in symptoms)
Clozaril/Clozapine	0.89
Solian/Amisulpride	0.73
Zyprexa/Olanzapine	0.56
Cobenfy/KarXT	0.56
Risperdal/Risperidone	0.55
Invega/Paliperidone	0.49
Abilify/Aripiprazole	0.41
Latuda/Lurasidone	0.36
Vraylar/Cariprazine	0.34
Rexulti/Brexpiprazole	0.26

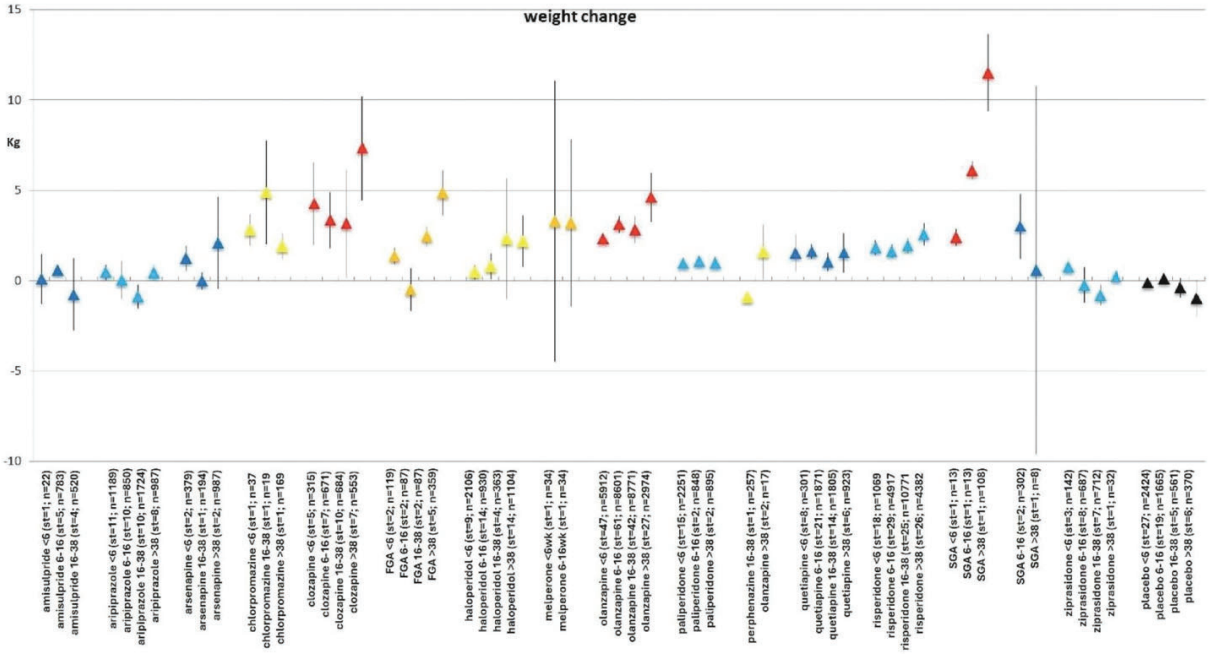
Amisulpride's effect size was greater than that of Cobenfy for the treatment of schizophrenia.

EUFEST, a European clinical trial published in 2005 in which 498 first-episode schizophrenia patients were randomized to receive haloperidol, amisulpride, olanzapine, quetiapine, or ziprasidone over 12 months, evaluated the primary endpoint of all-cause discontinuation rate, which is the number of patients who stopped taking their medications for any reason. Besides olanzapine, amisulpride had the lowest all-cause discontinuation rate over 12 months out of all drugs evaluated in this head-to-head comparison, supporting a favorable tolerability profile.



Amisulpride had a low discontinuation rate in the head-to-head EUFEST trial.

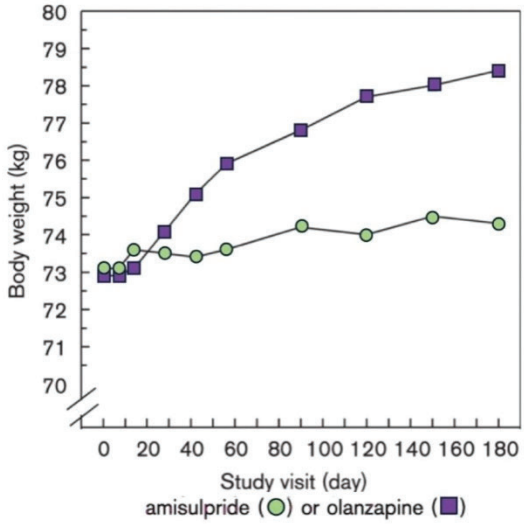
Amisulpride has also been shown to have a relatively low rates of EPS (11%), long-term weight gain, and cardiovascular risk compared with other second-generation antipsychotic drugs. In a 2014 head-to-head meta-analysis conducted by a third party comparing weight gain among antipsychotics, amisulpride had lower weight gain compared with other antipsychotic drugs across various outcome measures including body weight gain (in kg). The results comparing weight gain for amisulpride with that of other antipsychotics are highlighted in the chart below.



FGA = first generation antipsychotics; SGA = second generation antipsychotics; st= number of studies

Amisulpride had a lower weight gain compared with other antipsychotic drugs.

Additionally, in a third-party head-to-head trial completed in 2002 that compared long-term weight gain of amisulpride over six months to that of olanzapine, amisulpride weight gain exceeded that of olanzapine over the first 30 days of the study, and plateaued at approximately 1 kg, whereas weight gain with olanzapine continued to increase throughout the six-month period reaching a weight gain of approximately 5 kg, as shown in the graph below:



Amisulpride had lower weight gain than olanzapine in a third-party head-to-head trial.

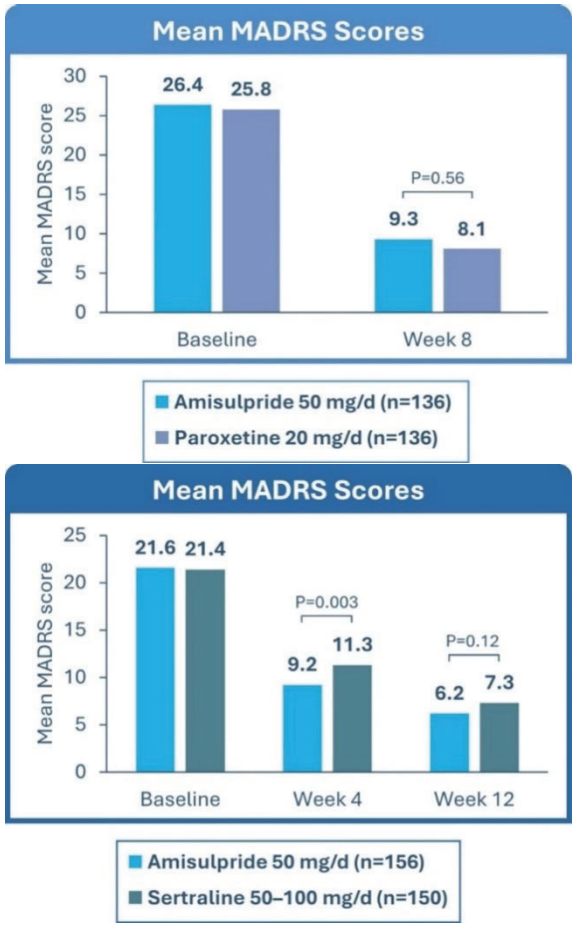
In addition, pharmacovigilance data on amisulpride from the United Kingdom covering 16,000 patient exposure years had 8 incidences of QT prolongation with all 8 events occurring in patients concurrently taking clozapine, a drug known to prolong the QT interval.

According to market research in 2024, amisulpride continues to be widely used in Europe. Among a select group of European countries including Germany, France, Italy, Spain, and several others, there were at least two million monthly prescriptions per year for amisulpride. Among these European prescriptions for amisulpride, our data suggest that approximately 60% are for schizophrenia and schizoaffective disorders (a mental health condition that includes symptoms of both schizophrenia and mood disorders), approximately 20% are for mood disorders, approximately 14% are for anxiety, and the remainder are for a variety of other indications.

Amisulpride has also been studied for the treatment of predominantly negative symptoms of schizophrenia in three independent placebo-controlled trials conducted by third parties. A trial conducted in 1995 evaluated two doses of amisulpride, 100 and 300 mg per day, versus placebo for six weeks of treatment. In this trial, the two amisulpride-treated arms showed a reduction in the Scale for the Assessment of Negative Symptoms, or SANS, of approximately 39 to 45 points compared with a reduction of 22 points in the placebo arm (p = less than 0.02). P refers to "p-value," the conventional method for determining the statistical significance of a result, which represents the probability that random chance caused the result (e.g., a p-value = 0.01 means that there is a 1% probability that the difference between the control group and the treatment group is purely due to random chance). Generally, a p-value less than 0.05 is considered statistically significant. The SANS scale is a 25-item scale that assesses negative symptoms across five domains: affective blunting, alogia, avolition-apathy, anhedonia-asociality, and attentional impairment. A trial conducted in 1999 evaluated two doses of amisulpride, 50 and 100 mg per day, versus placebo for 12 weeks of treatment. In this trial, the two amisulpride-treated arms showed a reduction in SANS of approximately 25 points compared with a reduction of 13 points in the placebo arm (p = 0.0002). A trial conducted in 1997 evaluated 100 mg per day of amisulpride versus placebo for 6 months of treatment. In this trial, the amisulpride-treated arm showed a reduction in SANS of approximately 34 points compared with a reduction of 17 points in the placebo arm (p = less than 0.0005).

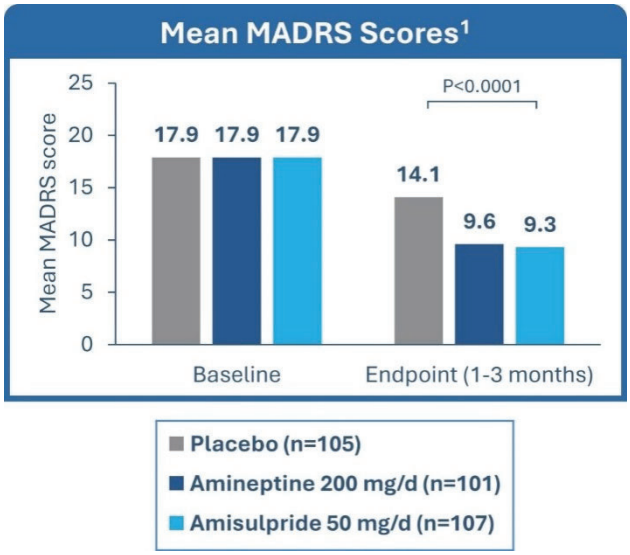
Amisulpride in Treating Mood Disorders

Amisulpride has been studied extensively in mood disorders. A 2002 head-to-head trial conducted by a third party found amisulpride to show similar reductions in mean MADRS scores as paroxetine (Paxil), a commonly used antidepressant and a 2001 head-to-head trial conducted by a third party found amisulpride to show higher reduction in mean MADRS scores compared to sertraline (Zoloft), a commonly used antidepressant, in treating dysthymia, as shown below:



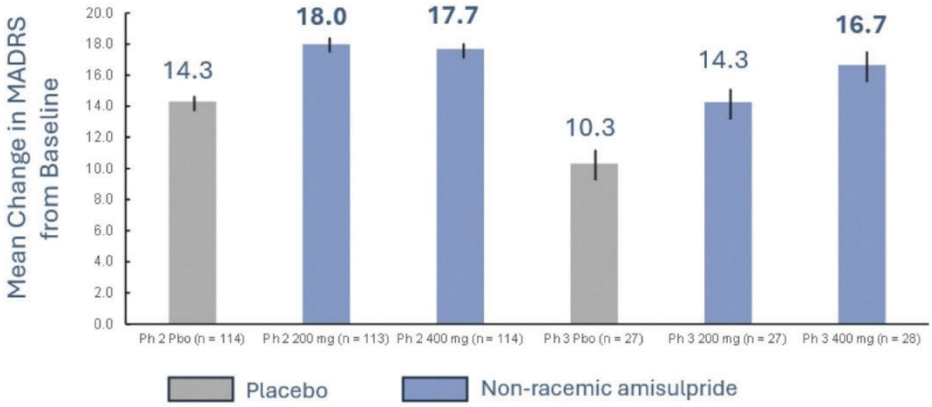
Amisulpride was demonstrated to be as effective as paroxetine and more effective than sertraline in third-party head-to-head trials.

Amisulpride has also been shown to be effective versus placebo, such as in a 1999 head-to-head trial conducted by a third party in dysthymia and major depression, which showed amisulpride and another study drug each leading to a statistically significant improvement over placebo on MADRS.



Amisulpride had an approximately 4.8-point MADRS delta versus placebo in a randomized controlled third-party trial in patients with MDD.

A non-racemic version of amisulpride was studied in bipolar depression. In a 2022 placebo-controlled proof-of-concept trial conducted by a third party in 341 patients across U.S., European, and Japanese clinical sites, non-racemic amisulpride demonstrated meaningful improvement over placebo on the MADRS in treating bipolar depression. Although the trial did not meet its primary endpoint, which was defined as MADRS delta versus placebo in United States and European patients, when results were analyzed for all patients across all geographies, a statistically significant benefit versus placebo in favor of non-racemic amisulpride was noted with a 3.4 to 3.7-point MADRS delta versus placebo and an approximately 18-point reduction in MADRS versus baseline in each of the two treatment arms. The mean reduction from baseline in the placebo arm in this trial was 14.3 points.



Non-racemic amisulpride demonstrated anti-depressant activity in two independent placebo controlled trials.

The placebo rate observed in this trial was higher than the average placebo rate from a recent set of bipolar depression trials, which was an approximately 12-point reduction in MADRS from baseline. We believe that the high placebo rate in this trial was in part a result of poor trial design and conduct. A Phase 3 trial was subsequently initiated by the third party with non-racemic amisulpride and though the trial was terminated prior to completion, results from 82 patients enrolled in the trial were reported. These results showed a 4.0 to 6.4-point MADRS delta versus placebo and an approximately 14 to 17-point reduction in MADRS versus baseline in the two treatment arms. Amisulpride and the non-racemic form studied in these two trials have been shown to be substantially similar in pre-clinical models.

It is widely recognized that episodes of major depression whether unipolar (as in MDD) or bipolar (as in bipolar depression) are characterized by a similar imbalance in the neurotransmitters serotonin, noradrenaline, and dopamine, regardless of the underlying pathophysiology of the disease. Additionally, third party prescription data which we

analyzed suggests that in 2023, there were at least two million monthly prescriptions of amisulpride in a subset of 16 continental European countries with considerable use in depression (approximately 16.2% of prescriptions) and approximately 3.4% of prescriptions were written for bipolar disorder despite the absence of an approval for this indication.

LB-102 is Designed to Improve Upon Amisulpride and Address its Limitations

While amisulpride is a clinically effective and well-tolerated drug, it has low BBB permeability that limits the amount of drug that can reach its desired target. As reported in a 2014 third-party study of 30 psychiatric drugs tested in an *in vitro* assay to estimate BBB permeability, amisulpride was the least effective at crossing a model of the BBB. This low permeability is one of the main factors that lead to high dosing of amisulpride, compared to other antipsychotic drugs, to achieve clinically meaningful BBB penetration. The recommended dose of amisulpride for acute schizophrenia ranges from 400 mg to 800 mg per day, which may be increased up to 1,200 mg per day. By comparison, clinically effective doses of other antipsychotic drugs with similar affinities for dopamine receptors are often much lower (e.g., 1.5 mg of Vraylar and 4 mg of Rexulti).

The high doses of amisulpride increase systemic exposure to the drug, contribute to some of its side effects, and limit its ability to be formulated into an LAI – there are currently no LAIs approved among the benzamide class of antipsychotics. Another drawback of amisulpride is that it is typically dosed twice-daily, which can lead to lower adherence relative to therapies with less frequent dosing schedules. Lower adherence can, in turn, lead to less efficacy of a drug in treating schizophrenia which can result in relapses.

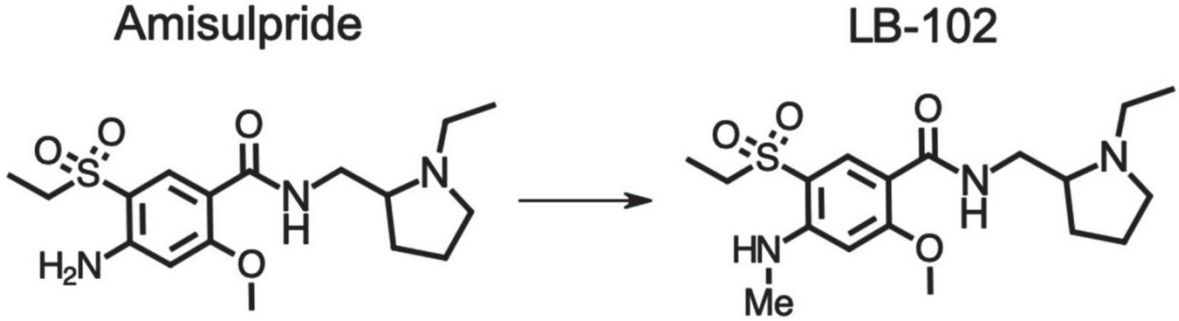
LB-102 for the Treatment of Schizophrenia

LB-102 Overview

LB‑102 is a patented small molecule with potential to be the first benzamide in the U.S. for the treatment of neuropsychiatric disorders. It was designed to optimize the therapeutic potential of selective D2/D3/5‑HT7 antagonism through improved CNS exposure, lower required doses, and once‑daily administration. While amisulpride has demonstrated strong efficacy and favorable tolerability, its clinical use has been constrained by limited blood–brain barrier penetration and the need for high systemic doses to achieve adequate receptor engagement.

LB-102 incorporates a targeted structural optimization intended to enhance blood–brain barrier permeability while preserving the desired receptor selectivity that underlies the clinical benefits observed with amisulpride. Improved CNS penetration enables LB-102 to achieve effective dopamine receptor engagement at substantially lower doses than amisulpride, reducing systemic exposure and supporting a once‑daily dosing schedule with potential to improve tolerability and adherence.

The following chart shows the molecular structures of amisulpride and LB‑102, illustrating the targeted structural modification incorporated into LB‑102.



LB-102 is a methylated and patented derivative of amisulpride.

In Vitro Receptor Binding of LB-102

In vitro binding of LB-102 to target central nervous system, or CNS, receptors was found to be similar to that of amisulpride. LB-102 bound most strongly to the dopamine D_2 and D_3 receptors, with a K_i of 0.82 nM (compared to

amisulpride's reported K_i of 1.1 nM), and had a similar affinity for the 5-HT7 receptor with a K_i of 31 nM (compared to amisulpride's reported K_i of 44 nM). Compared to other commonly prescribed antipsychotic drugs, both LB-102 and amisulpride have weaker binding to other off-target CNS receptors that are commonly associated with adverse side effects such as anxiety, weight gain, or metabolic syndrome such as 5HT2C.

In Vivo Activity of LB-102 is Similar to Amisulpride

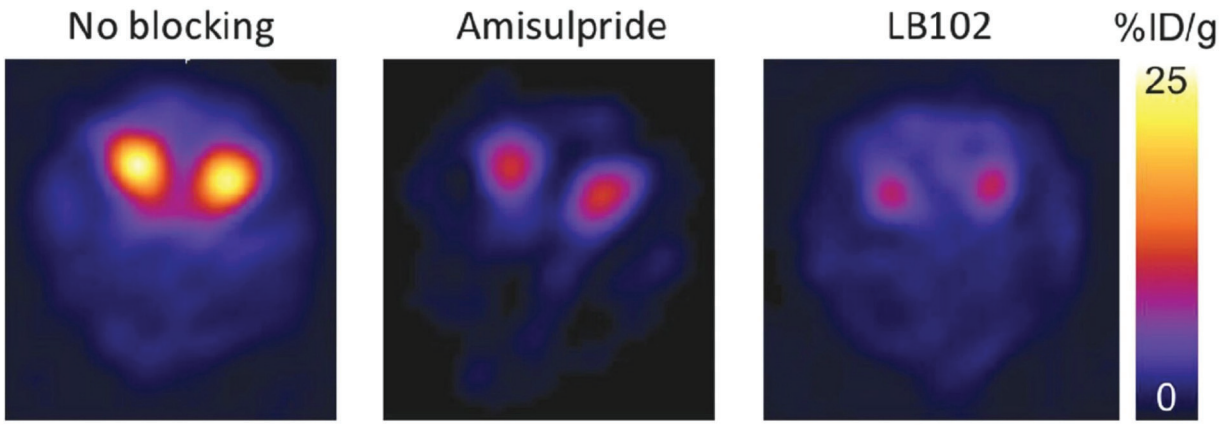
We evaluated LB-102 in the Locomotor Activity, or LMA, rat model of hyperactivity, often used to predict clinical activity in treating positive symptoms of schizophrenia. In the LMA, rats dosed with amphetamine alone displayed hypermobility, while rats additionally dosed with antipsychotic drugs showed more normal, calmer activity.

LB-102 had equivalent or better results than similar doses of amisulpride in the LMA model of hyperactivity. In our head-to-head preclinical rat model of cognition, the Novel Object Recognition model, and in a mouse model of stereotypy or excessive repetition, the Apomorphine Induced Climbing model, we observed that the effects of treatment with LB-102 were statistically indistinguishable from that of amisulpride.

Brain Penetration and Dopamine Receptor Occupancy of LB-102

The ability of LB-102 to cross the BBB was estimated using a standard *in vitro* membrane permeability assay. In this assay, the permeability of LB-102 was approximately 200-fold greater than that of amisulpride.

An *in vivo* head-to-head study in mice using positron emission tomography, or PET, demonstrated that at a dose of 100 mg/kg of both LB-102 and amisulpride, LB-102 had greater dopamine receptor occupancy in the brain than amisulpride, as shown below. We believe these results supported dosing LB-102 at much lower levels than amisulpride to achieve the desired effect on symptoms of schizophrenia.



LB-102 reduced the binding of a dopamine receptor PET ligand in the brain by two-fold compared to amisulpride. More faint luminescence represents greater dopamine receptor occupancy. %ID/g represents the percent injected dose per gram.

Schizophrenia

Overview and Disease Background

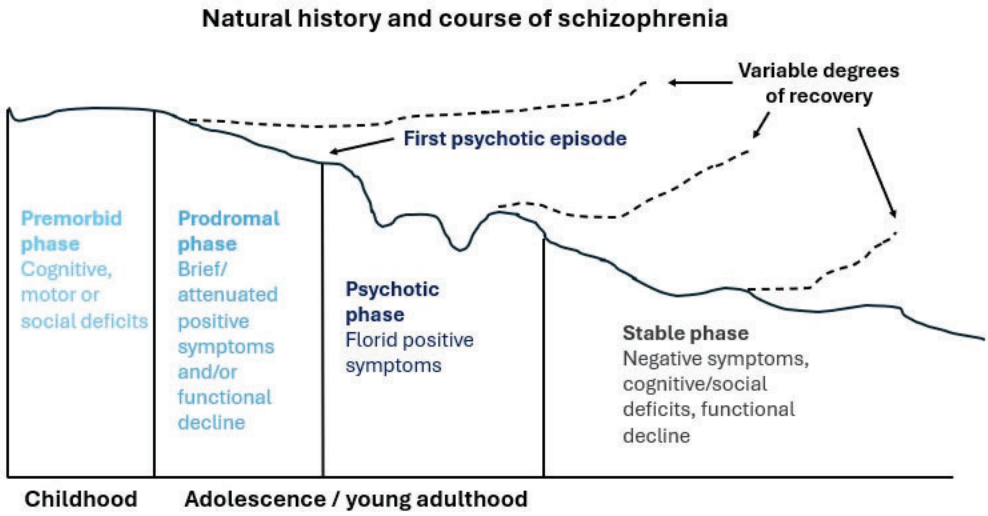
Schizophrenia is a chronic, severe, complex, and debilitating psychiatric disorder that affects approximately 1% of the U.S. population and is a leading cause of disability. Symptoms of schizophrenia are typically grouped into three categories:

- Psychotic or positive symptoms, such as hallucinations, delusions, thought disorder, and movement disorder;
- Negative symptoms, such as loss of motivation, interest, or enjoyment in daily activities, withdrawal from social life, and difficulty in showing emotions; and
- Cognitive symptoms, such as problems in attention, concentration, and memory.

While antipsychotic drugs are commonly used to treat schizophrenia, there is currently no cure for schizophrenia, which means the disease must be managed with life-long therapy, increasing the importance of therapies that can improve compliance rates and dosing challenges.

Schizophrenia is typically diagnosed in the late teen years to early thirties and tends to emerge earlier in males than in females. The estimated average potential life expectancy for individuals living with schizophrenia in the United States is reduced by as much as 29 years in comparison to the general population. This significant reduction is believed to be due to multiple factors, including a high rate of other comorbidities and an increased risk of accidental death and suicide. An estimated 5% of people with acute schizophrenia die by suicide, which is a rate approximately 350 times higher than the general population.

The progression of schizophrenia usually follows a typical pattern. The prodromal phase refers to the early stage of the disease where subtle changes in behavior and cognitive function occur but before psychotic symptoms, such as hallucinations or delusions. This is the stage when the first warning signs of the disease can be identified. The prodromal phase ends when the patient experiences the first active phase which is characterized by positive symptoms, including hallucination, delusions, and disordered thinking. Recent studies have shown that if treated properly early in the course of their illness, most patients recover from this first episode and have a substantial reduction, or even remission of psychotic symptoms. While in this “stable” phase after recovery from an acute episode, it is estimated that 13% to 48% of patients continue to have residual symptoms. At this point, the patient may experience cycles of active disease, characterized by positive symptoms, and periods of stability, potentially with persistent negative symptoms. A meta-study showed that 55% of people with schizophrenia required hospitalization over an average follow-up of seven years after their first episode. With each relapse, the disease worsens, and the patient typically is unable to recover to the same level of health as prior to the active episode. Over years of experiencing these cycles, most patients deteriorate, experiencing worsening symptoms and health outcomes. A therapy that reduces the number of relapses a patient experiences has the potential to provide a significant and life-long benefit. The figure below depicts a graphic illustration of these phases.



Pathophysiology of Schizophrenia

One of the main hypotheses for the pathophysiology leading to schizophrenia is an imbalance in neurochemical signaling in the brain, including serotonin, dopamine, and glutamate. Specifically, schizophrenia is associated with an imbalance of dopaminergic pathways at the D_2 receptor subtype. Increased dopamine activity in certain parts of the brain can contribute to positive symptoms of schizophrenia. In contrast, reduced dopamine activity in other parts of the brain may cause negative and cognitive symptoms. Detailed understanding of the specific changes in dopamine signaling that lead to schizophrenia is limited by the relative inaccessibility of methods to assess signaling pathways in the brain, the heterogeneity of psychological responses, and the lack of highly translatable animal models. Since the 1970s, clinical trials with haloperidol, risperidone, and olanzapine, among others, have conclusively demonstrated that antagonism of the dopamine D_2 receptor can improve symptoms of schizophrenia.

Schizophrenia with Predominantly Negative Symptoms

Negative symptoms are a core component of schizophrenia and are distinct from positive symptoms. They account for a large part of the long-term morbidity and poor functional outcomes. It is estimated that up to 60% of people with schizophrenia may have predominantly negative symptoms that are clinically relevant and require treatment equating to approximately 1.3 million people in the United States. In a meta-analysis for 20 placebo-controlled trials of second-generation antipsychotic drugs, 62% of patients were experiencing predominantly negative symptoms and after six weeks of treatment. Negative symptoms are linked to worse functional outcomes in occupational and academic performance, household integration, social functioning, participation in activities and quality of life.

People living with negative symptoms of schizophrenia are considered to have a higher burden of illness, which may be partially attributed to the limited number of effective treatment options for this population. To date, there are no FDA approved treatments for predominantly negative symptoms of schizophrenia.

Cognitive Impairment Associated with Schizophrenia, or CIAS

CIAS, which encompass problems with attention, concentration, and memory, is a major burden for patients and negatively impacts many aspects of a patient's life. Cognitive impairment is a core feature and leading cause of functional disability in schizophrenia and other neuropsychiatric disorders. Antipsychotic drugs are the standard-of-care treatment for schizophrenia but typically only address positive symptoms. So far there are no approved pharmacotherapies for the treatment of CIAS. More than 80% of people with schizophrenia have cognitive symptoms of some kind, equating to approximately 1.8 million patients in the United States.

Limitations of Current Treatments for Schizophrenia

Antipsychotic drugs are commonly classified as first-or second-generation drugs. First-generation antipsychotic drugs function primarily as antagonists or partial agonists of dopamine receptors. These drugs, some of which were discovered in the 1950s, primarily address positive symptoms of schizophrenia. Current literature suggests a high correlation between dopamine receptor binding and clinical potency; typically, 60% to 80% dopamine receptor occupancy is the target range for efficacy in treating schizophrenia. Second-generation antipsychotic drugs are typically dual serotonin and dopamine antagonists. The multimodal mechanism of action of these drugs allows them to treat symptoms of schizophrenia with a lower incidence of EPS. More recently, additional mechanisms have entered clinical practice, including M1/M4 muscarinic agonists, representing a mechanistically different approach. However, their clinical role will depend on real-world experience with tolerability, durability of effect, ease of switching and simplicity of dosing. Existing antipsychotic drugs fall short of the ideal profile, as most currently approved medications have significant side effects, primarily address positive symptoms of schizophrenia, and are often not effective in treating negative and cognitive symptoms. Negative symptoms are a core component of the disease, and it is estimated that up to 60% of patients may experience clinically relevant negative symptoms that require treatment. Negative symptom severity has been linked to worse functional outcomes in areas such as impaired occupational and academic performance, social functioning, and quality of life. Despite the prevalence and seriousness of this component of schizophrenia, there are few treatment options that effectively address negative symptoms. Additionally, cognitive impairment affects approximately 80% of schizophrenia patients. There are currently no approved drugs for cognitive impairment.

Both first- and second-generation antipsychotic drugs are often associated with sedation leading to cognitive dulling, dry mouth, constipation, EPS including akathisia (inability to remain still), and sexual dysfunction. Some side effects are severe or even life-threatening, such as dystonia, a form of EPS (involuntary muscular contraction), tardive dyskinesia (movement disorder that causes involuntary facial tics), and weight gain, which can lead to hyperlipidemia (high levels of lipids in the blood) and cardiac arrhythmias (abnormal heart rhythms). The combination of side effect profile, as well as poor efficacy and tolerability, results in approximately half of all schizophrenia patients not adequately responding to current antipsychotic drugs. High rates of failure in achieving a clinically meaningful response with existing therapeutics, the evolution of patient symptoms over time, inconvenient dosing regimens and significant side effects cause patients with schizophrenia to switch medications or layer on additional antipsychotic drugs frequently. Aside from suboptimal efficacy and tolerability, some current therapies also accompany inconvenient administration profiles, such as twice-a-day dosing or the need to be taken with food.

Together, these limitations lead to significant issues with patient adherence. One study showed that one-third of patients admitted to the hospital after their first psychotic episode of schizophrenia were non-adherent to their treatment six months after discharge. A multitude of studies have shown the serious outcomes that accompany non-adherence to medication, including impairment, hospitalization, higher risk of suicide, longer time to remission, poorer prognosis, loss of job, dangerous behavior, arrest, violence, drug and alcohol consumption, psychiatric emergences, poor mental performance, and low satisfaction with life. Interruptions in treatment as short as one to 10 days has been associated with an increased risk of hospitalization.

Nearly 50% of all schizophrenia patients fail to respond adequately to existing therapies, many of which have limited efficacy against the range of symptoms associated with the disease. Most antipsychotic drugs are associated with significant side effects that drive high rates of treatment discontinuation. Approximately 74% of schizophrenia patients discontinue their medications within 18 months of starting treatment due to their perceived lack of efficacy or burdensome side effects. Since these medications only treat symptoms of schizophrenia and cannot eliminate the underlying pathology, their discontinuation results in symptom recurrence. As a result of these high rates of discontinuation, there is a significant amount of switching therapeutic treatments. Taken together, the limitations of currently available antipsychotic therapies highlight the need for new treatment options capable of delivering rapid and sustained symptom control while improving long-term tolerability, adherence, and real-world effectiveness. Beyond managing positive symptoms, there remains a substantial unmet need for therapies that can meaningfully address the negative and cognitive symptoms that are highly prevalent in schizophrenia and strongly associated with functional disability and reduced quality of life. In the table below, we show the efficacy and side effect profiles of branded antipsychotic drugs approved for treatment of schizophrenia in the United States based on the approved labels.

Drug	Mechanism of Action	Baseline PANSS	Reduction in PANSS vs. Baseline	Placebo-Corrected Reduction in PANSS	Notable Lab Findings and Side Effects	Recommended Dosage	Dosing Frequency
Caplyta	Dopamine Receptor Antagonist	88.1 (Trial 1) 90.0 (Trial 2)	13.2 (Trial 1) 14.5 (Trial 2)	5.8 (Trial 1) 4.2 (Trial 2)	Sedation (24%), dry mouth (6%); EPS (6.7%)	42 mg	Once-daily
Cobenfy	M1/M4 Muscarinic Receptor Agonist	98.2 (Trial 1) 96.9 (Trial 2)	21.2 (Trial 1) 20.6 (Trial 2)	9.6 (Trial 1) 8.4 (Trial 2)	Nausea (19%), dyspepsia (18%), constipation (17%), vomiting (15%), hypertension (11%), EPS (non-akathisia, 2%)	Up to 125 mg/30 mg	Twice-daily, 1 hour before or at least 2 hours after meals
Rexulti	Dopamine Receptor Partial Agonist	94.7 (Trial 1) 95.0 (Trial 2)	19.7 (Trial 1) 20.0 (Trial 2)	7.6 (Trial 1) 6.5 (Trial 2)	Akathisia (6%), weight increase (4%), diarrhea (3%), dyspepsia (3%), tremor (3%), blood creatinine phosphokinase increase (2%); sedation (2%)	4 mg	Once-daily
Vraylar	Dopamine Receptor Partial Agonist	97.1 – 96.7 (Trial 1) 96.1 – 95.7 (Trial 2) 96.3 (Trial 3)	19.4 – 22.3 (Trial 1) 20.2 – 23.0 (Trial 2) 22.8 – 25.9 (Trial 3)	7.6 – 10.4 (Trial 1) 6.0 – 8.8 (Trial 2) 6.8 – 9.9 (Trial 3)	EPS (15-19%)*, akathisia (9-13%)	1.5 - 6 mg	Once-daily

Note: Characteristics of antipsychotic drugs approved for the treatment of schizophrenia. PANSS is a measure of symptoms in schizophrenia patients including positive and negative symptoms, and general psychopathology, and reduction in PANSS v. baseline is a measure of efficacy of antipsychotic drugs. The change in PANSS score has been used as the primary endpoint in registrational trials of antipsychotic drugs, as it provides a comparative measure against baseline; a higher change from baseline can suggest greater improvement in patient symptoms. As this assessment requires patients or raters to undertake a questionnaire regarding symptoms at protocol specified timepoints in the trial, it is, however, inherently subjective, which can increase the variability of clinical results across clinical trials and creates a significant degree of uncertainty in determining overall clinical benefit. Caplyta efficacy data is based on four-week data from one Phase 2 trial and one Phase 3 trial (n=335; n=450). Cobenfy data is based on five-week data from two Phase 3 trials (n=236; n=234). Rexulti data is based on six-week data from two Phase 3 trials (n=674 total). Vraylar data is based on six-week data from three Phase 3 trials (n=1,655 total). Akathisia is a form of EPS but is reported separately in a number of product labels.

Because of the fragility of the patient population and high rates of non-adherence, tolerability and ease of use is an important factor for schizophrenia medications. Studies have shown that medication-related obesity, distress related to weight gain, and cognitive impairment are associated with increased rates of non-adherence. Caplyta, Rexulti and Vraylar all contain warnings in their labels regarding metabolic changes, including weight gain. Somnolence, or sedation, are among the most frequent adverse events observed with Caplyta. Despite the burdensome side effects associated with these antipsychotic drugs, they are still commonly used, with patients frequently switching between different medications in search of the right balance of tolerability and efficacy. We believe a medication with an improved tolerability profile, rapid onset and sustained efficacy, including with respect to negative symptoms or cognition, or both, have the potential to provide a much-needed alternative to currently available therapies. We also believe a simple administration profile, once-daily dosing with no food effect, would provide a significant advantage as it has the potential to improve patient adherence and, therefore, improve long-term outcomes. Additionally, an LAI has the potential to further simplify the patient experience and improve medication adherence. Currently, there are no LAIs

available for Caplyta, Cobenfy, Rexulti or Vraylar although several are in development. In addition, there are no LAIs among the benzamide class of antipsychotic drugs currently available or in development worldwide.

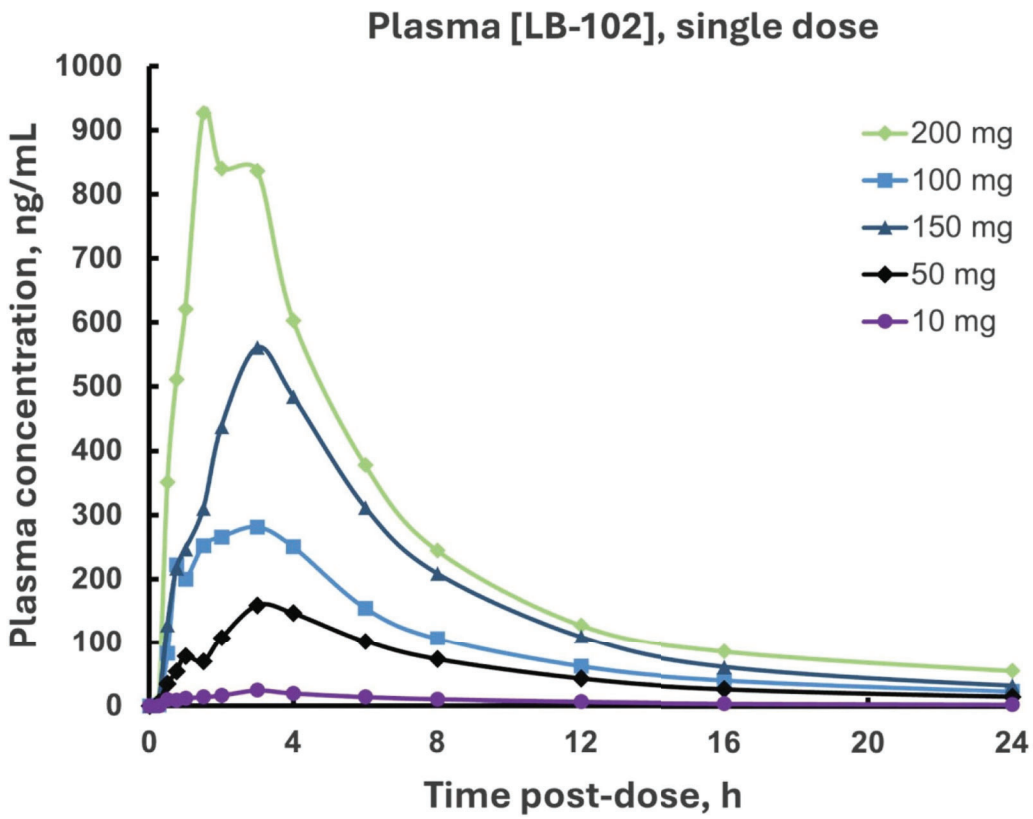
Despite the availability of several generic and branded treatments for schizophrenia, there remains a significant unmet need. Only 20% of people with schizophrenia report favorable treatment outcomes. The remaining population experiences numerous psychotic episodes, chronic symptoms and a poor response to antipsychotic drugs. Additionally, patients who experience predominantly negative symptoms and those with treatment-resistant schizophrenia live with a significant disease burden that cannot be sufficiently alleviated with currently available treatments. There are no approved therapies in the U.S. for the treatment of predominantly negative symptoms of schizophrenia or cognitive impairment associated with schizophrenia. We believe a treatment that is effective, tolerable, supports adherence in a fragile population and can address negative and residual symptoms could become a mainstay of schizophrenia treatment. We believe LB-102 has the potential to meet this profile.

LB-102 Clinical Data

Completed Phase 1 Trial of LB-102 in Healthy Volunteers

We conducted a Phase 1, randomized, placebo-controlled, double-blinded clinical trial in the United States to evaluate the safety, tolerability, and pharmacokinetics of oral administration of LB-102 in 64 healthy volunteers after submitting an IND in October 2019 and receiving approval to proceed in December 2019. In the single ascending dose, or SAD, portion of this trial, cohorts of six volunteers received doses ranging from 10 mg up to 200 mg. In the multiple ascending dose, or MAD, portion of this trial, cohorts of six volunteers received doses of 50 mg to 100 mg twice-daily for one week. In total, 48 volunteers were dosed with LB-102.

In September 2020, we announced the clinical results of this Phase 1 trial. The half-life of LB-102 was slightly greater than 12 hours, and maximum drug levels were observed approximately three hours after administration. We observed the plasma exposure of 50 mg of LB-102 to be 1,648 ng*h/mL. In a previous third-party study of amisulpride, plasma exposure was reported at 667 ng*h/mL. The chart below shows the pharmacokinetic profile of LB-102 in healthy volunteers from the SAD portion of this trial.



Pharmacokinetics of LB-102 in healthy volunteers.

Analyses of the MAD portion of the trial demonstrated that peak-trough concentrations of LB-102 plateaued before dosing on Day 4. LB-102 accumulated moderately after multiple doses but less than what has been reported for amisulpride. Exposure to LB-102 increased in a dose-proportional manner.

In this Phase 1 trial, LB-102 was generally well-tolerated. All treatment emergent adverse effects, or TEAEs, were either mild or moderate. TEAEs included events typically associated with dopamine antagonists. At doses higher than those studied in our Phase 2 trial and higher than those which we are evaluating in our Phase 3 trial, moderate dystonia and QT prolongation, which is a measure of delayed repolarization of the Q and the T waves in electrocardiogram, were observed. Consistent with other antipsychotic drugs that act as dopamine antagonists, use of LB-102 resulted in elevated serum prolactin levels. Subjects with moderate dystonia were treated with either Benadryl or Cogentin.

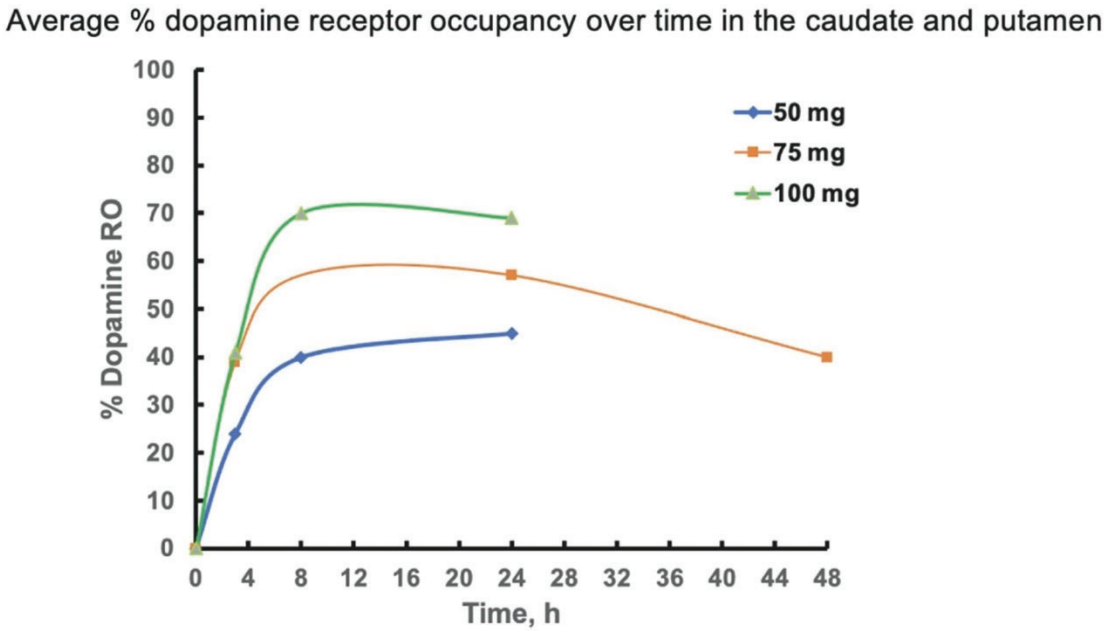
At 50 mg and 100 mg QD, two of the doses evaluated in our Phase 2 trial (and the doses being evaluated in our Phase 3 trial) we observed no adverse events associated with QT prolongation, sedation, weight gain or EPS in our Phase 1 trial. Prolactin elevation, a common laboratory finding of most antipsychotic drugs that act as dopamine antagonists that is believed to be the result of inhibition of dopamine receptors in the pituitary, was observed at all those doses.

QT prolongation refers to the lengthening of the QT interval in an electrocardiogram, during which interval, the heart recovers from one heartbeat and is preparing for the next heartbeat. The QT interval is a vulnerable phase in the electric cycle of the heart, and prolongation of this interval may lead to serious side effects. Amisulpride has been associated with QT prolongation. Although the mechanism linking amisulpride to this adverse event is not known, amisulpride is a weak inhibitor of human ether-a-go-go-related gene (hERG) potassium channels, and it has been shown that QT prolongation is dependent on amisulpride systemic exposure. At therapeutic doses of amisulpride up to 1,200 mg/day, literature reports of cardiac toxicity due to QT prolongation are extremely rare.

Completed Phase 1b PET Imaging Trial

We conducted a Phase 1b dopamine receptor occupancy trial of LB-102 in the United States using PET imaging to assess dopamine receptor occupancy in the brains of healthy volunteers. In this trial, the ability of LB-102 to bind to dopamine receptors was measured directly by displacement of the dopamine receptor PET ligand ^{11}C-raclopride. This trial enrolled four cohorts of healthy volunteers dosing from 50 mg to 100 mg per day. The first three cohorts in this trial received a single dose of LB-102; in the fourth cohort, volunteers were dosed once-daily for four days. Of the four healthy volunteers in the fourth cohort, two received one daily dose of 50 mg, and two received one daily dose of 100 mg, each over four days.

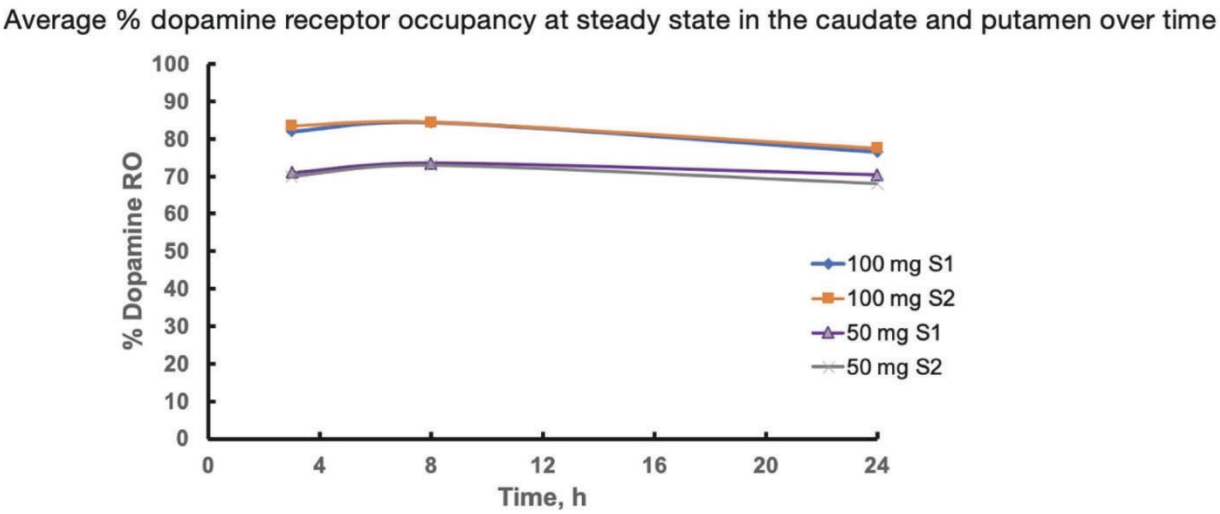
We announced data from our Phase 1b trial in December 2021. We observed that single doses of LB-102 led to a linear, dose-dependent dopamine receptor occupancy that achieved maximal levels at approximately eight hours post-dose and persisted for at least 24 hours, as shown in the figure below. Based on results from our 50 mg single-dose cohort, we measured dopamine receptor occupancy at 48 hours for the 75 mg single-dose cohort. These results and the previously observed plasma half-life of approximately 12 hours supported our decision to develop LB-102 for once-daily dosing.



For cohorts one, two, and three, single doses of LB-102 led to dose-dependent dopamine receptor occupancy.

We evaluated dopamine receptor occupancy under steady-state conditions in our fourth dose cohort. We observed that the receptor occupancy following the Day 4 dose was relatively consistent over 24 hours in all four volunteers. Under steady-state conditions, at the 50 mg dose of LB-102, the average receptor occupancy was approximately 70%, and at the 100 mg dose, it was approximately 80%. Previous reports analyzing receptor occupancy of multiple antipsychotic drugs have found that occupancies of 60% to 80% correlate with maximum efficacy and tolerability in the treatment of schizophrenia. Receptor occupancy above 80% can be associated with an increased risk of EPS.

The following chart depicts the dopamine receptor occupancy in the fourth cohort of our Phase 1b trial.



Dopamine receptor occupancy following repeat dosing of LB-102. S1 and S2 indicate Subject #1 and Subject #2, respectively.

Dopamine receptor occupancy persisted over 24 hours after the final dose of LB-102 was administered under steady-state conditions and yielded a consistent engagement of dopamine receptors not always observed in other antipsychotic drugs.

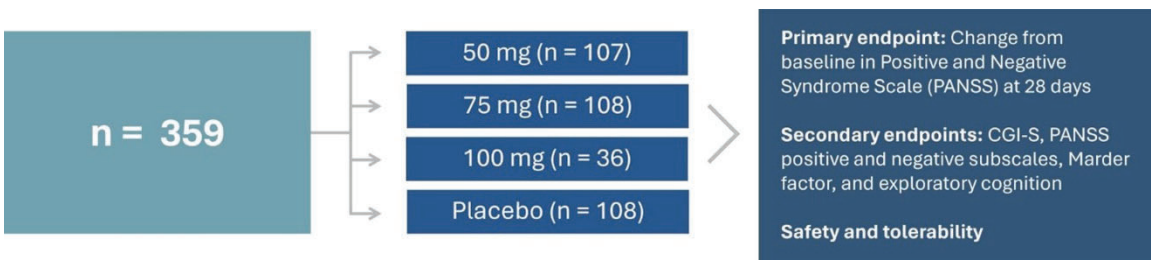
Completed Phase 2 NOVA-1 Trial of LB-102 in Acute Schizophrenia

Clinical Trial Design

Based on the positive results of our Phase 1 trial, we conducted a four-week in-patient, double-blind, randomized, placebo-controlled Phase 2 trial of LB-102 in acute schizophrenia patients and total PANSS scores between 80 and 120, who have shown good response to previous antipsychotic drugs other than clozapine in the prior 12 months. The Phase 2 trial enrolled 359 participants at 25 clinical trial sites in the United States, who were randomized 3:3:1:3 across four cohorts, three doses of LB-102 and placebo (n=108). Prior to initiating dosing, patients underwent a seven-day wash-out period, a length of time that an enrolled patient may not receive any treatment before they begin the trial. Because we were able to achieve 70% receptor occupancy under steady-state conditions with a once-daily dose of 50 mg of LB-102, we chose to advance this as the lowest dose in our Phase 2 trial (n=107 participants) while exploring the potential of higher doses at 75 mg (n=108 participants) and 100 mg (n=36 participants). Based on previous results, we believed that there was a potential for the 100 mg dose to result in receptor occupancy above 80%. As a result, we chose to limit the number of participants enrolled at this dose level while maintaining enough patients to provide insight into the therapeutic potential of this dose. Participants in each cohort received once-daily doses for four weeks. All patients started at the planned dose level without titration.

The primary endpoint of this trial was efficacy of the 50 mg and 75 mg doses of LB-102 compared to the placebo, as measured by change from baseline in PANSS total score at four weeks. The secondary endpoints included change from baseline in the Clinical Global Impression-Severity, or CGI-S (which measures the severity of schizophrenia) as measured by clinicians, and change from baseline on the PANSS subscale and Marder factor scores at four weeks. The 100 mg dose cohort was exploratory and was intended to characterize safety at the higher dose. However, we analyzed the 100 mg cohort with the same statistical rigor, including sensitivity analyses, applied to the 50 and 75 mg cohorts. We also evaluated the safety and pharmacodynamics of LB-102.

The following depicts our Phase 2 NOVA-1 trial design:

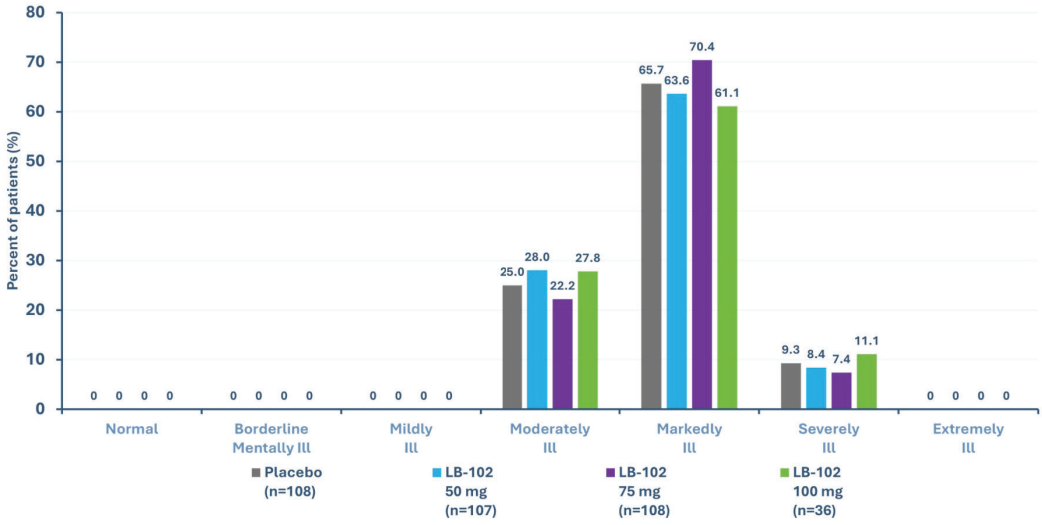


The topline results from the trial were announced in January 2025. Based on the design of this clinical trial, the results discussed below, and positive feedback from FDA as part of our end-of-Phase 2 interaction, we believe this Phase 2 trial may serve as one of two adequate well-controlled clinical trials of LB-102 required for approval. In addition to our 6-week Phase 3 trial, the design of which we shared with the FDA as part of our end-of-Phase 2 interaction, we anticipate the FDA will require 1,500 patient exposures to support an approval in schizophrenia. We expect to accrue these patient exposures through the Phase 3 and long-term OLE trials, the supportive Phase 1 trials and trials in other indications.

Demographics and Patient Characteristics

Of the 359 participants enrolled in our Phase 2 trial, 81% (n=290) were male and the average age was 39.1 years. Participants were diagnosed with schizophrenia a minimum of two years prior to enrollment in the trial with an average time since diagnosis of 15.8 years. The baseline PANSS scores were balanced across all four cohorts with mean measurements of 93.8, 93.9, 93.6 and 93.9 for the placebo, 50 mg, 75 mg and 100 mg cohorts, respectively. Patients with schizophrenia during an acute symptomatic episode is measured as 80 to 120 on the PANSS scale. If a patient drops below 80, they are no longer considered to be in the acute phase of the disease. There were several psychiatric and neurological disorders diagnosed in greater than 5% of the participant population prior to the trial including insomnia (74.1%), anxiety (58.8%), depression (32.9%), agitation (30.1%), and headache (40.1%).

We also used the CGI-S total score to measure the severity of schizophrenia in participants at baseline and weekly for the four weeks of the trial. Using the CGI-S, the investigator rated the participants' severity of illness, including behavior, symptoms, and function, over the past week on a scale of one to seven, with seven being the most severe. All participants were categorized at least as moderately ill, or a 4 on the CGI-S scale, with the majority of participants (range of 61.1% to 70.4% across the four cohorts) categorized as being markedly ill, or a 5 on the CGI-S scale, at baseline.

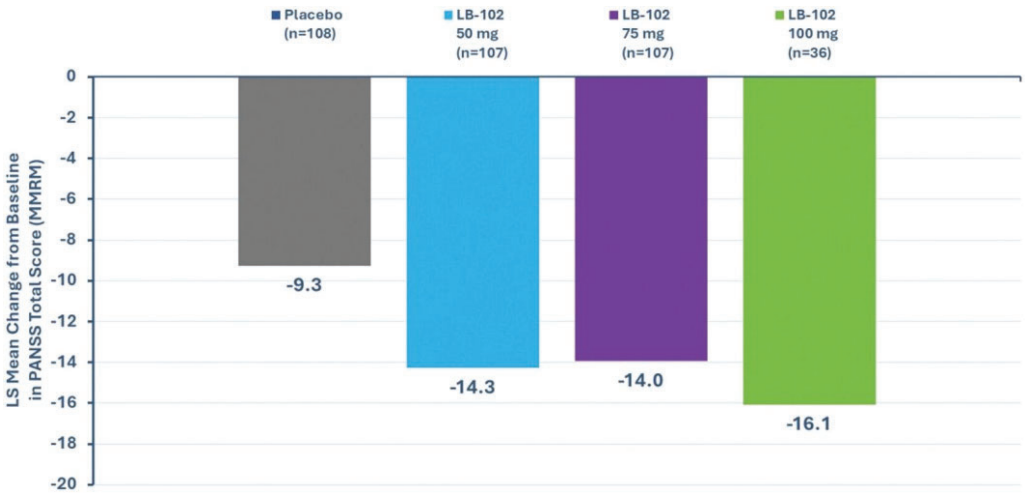


CGI-S Scores at baseline.

Efficacy Results

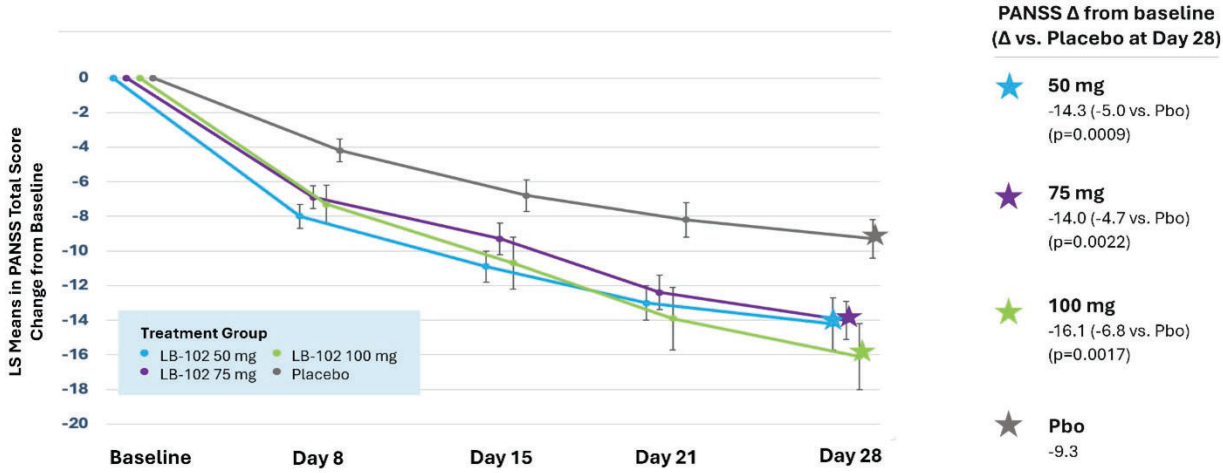
Primary Endpoint

The clinical trial achieved the primary endpoint of change from baseline in PANSS total score at four weeks. The least squares mean change from baseline at Week 4 was a 14.3-point decrease and 14.0-point decrease in PANSS score for the 50 mg and 75 mg cohorts, respectively. The exploratory 100 mg cohort showed a 16.1-point decrease in PANSS total score at Week 4. The placebo cohort had a 9.3-point decrease in PANSS total score. We included a number of measures in this Phase 2 trial to reduce the risk of an elevated placebo rate including consistent, frequent, and close engagement with clinical sites, the use of a third-party vendor to help identify and exclude professional patients from the trial, and a centralized review of PANSS ratings to ensure consistency and quality control throughout the trial. When adjusted for placebo-response, the 50 mg cohort achieved a five-point decrease (p=0.0009) and the 75 mg cohort achieved a 4.7-point decrease (p=0.0022) in PANSS total score. Despite the highest dose cohort being exploratory and not sized to detect a statistically significant difference, the 100 mg cohort demonstrated a 6.8-point decrease (nominal p=0.0017) in PANSS total score when adjusted for placebo, which did achieve statistical significance.



Least square (LS) mean change from baseline in PANSS total score.

The decrease in PANSS total score was observed as early as the first measurement on Day 8 with improvement seen through Week 4 across all three dose cohorts. Improvements in PANSS were statistically significant versus placebo at each timepoint measured throughout the study for all doses of LB-102.



Change in PANSS total score from baseline over time.

At Week 4, the 50 mg, 75 mg, and 100 mg groups showed effect sizes of 0.61, 0.41, and 0.83, respectively, as highlighted in the table below. Effect size is calculated by taking the difference in average observed PANSS change among completers between two groups (an active treatment arm and placebo) and dividing it by a single measure of variability that combines both groups' spreads—also called the observed pooled standard deviation. The observed pooled standard deviation averages how much individual patients' score changes scatter around their group's mean. Clinicians value effect size because it conveys not just how large the average PANSS improvement is, but also how consistently patients respond. Even if two treatments reduce PANSS by the same amount on average, the one with less scatter (i.e., a lower observed pooled standard deviation) will have a higher effect size—and gives a clinician more confidence that a higher proportion of patients will see that same benefit.

Dose of LB-102	Effect Size versus Placebo
50 mg	0.61
75 mg	0.41
100 mg	0.83

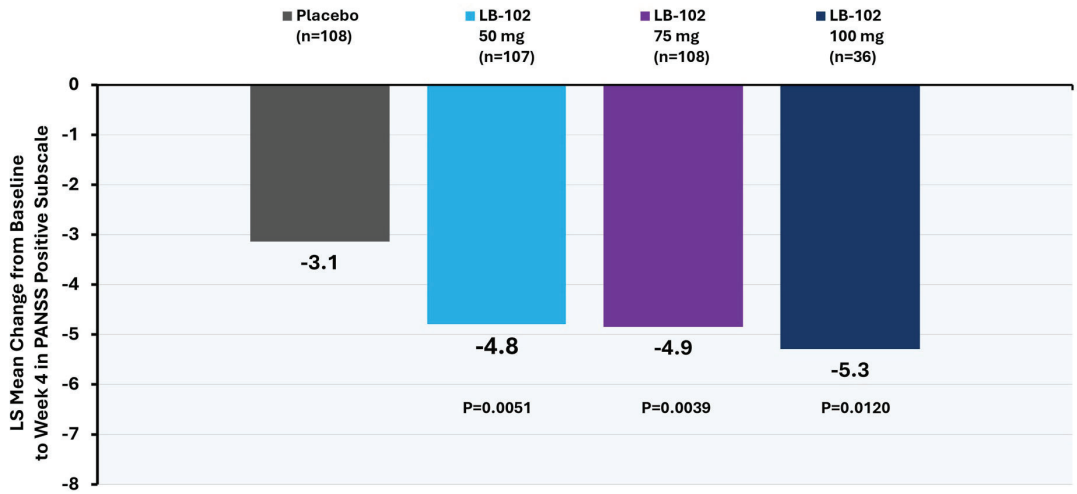
Effect Size versus Placebo in our Phase 2 trial.

We also calculated effect size versus placebo based on all patients with at least one post-baseline PANSS assessment combining both observed and imputed data and yielding effect sizes of 0.50 at 50 mg, 0.45 at 75 mg, and 0.64 at 100 mg.

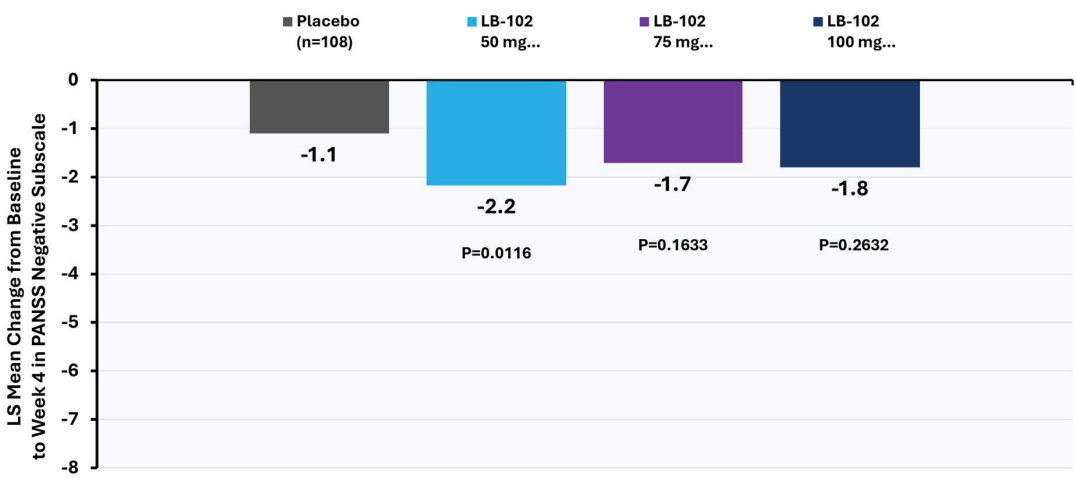
Secondary Endpoints

Within this trial, responders were defined as those who had a 20% or greater reduction in PANSS score at Week 4 (floor-adjusted). The three dose cohorts achieved a responder rate of 57.1% (p=0.0257), 53.6% (p=0.0213), and 78.3% (p=0.0014) for the 50 mg, 75 mg, and 100 mg dose cohorts, respectively, compared to a responder rate of 38.7% for the placebo cohort.

We also assessed response to treatment with LB-102 using PANSS subscales for positive and negative symptoms, respectively. Looking specifically at positive symptom response, we observed a 4.8-point decrease (p=0.0051), 4.9-point decrease (p=0.0039), and 5.3-point decrease (p=0.0120) in the PANSS positive subscale for the 50 mg, 75 mg, and 100 mg dose cohorts, respectively, compared to a 3.1-point decrease in the placebo cohort. When looking at the negative symptom PANSS subscale, we observed a 2.2-point decrease (p=0.0116), 1.7-point decrease (p=0.1633), and 1.8-point decrease (p=0.2632) in the 50 mg, 75 mg, and 100 mg dose cohorts, respectively, compared to a 1.1-point decrease in the placebo cohort.



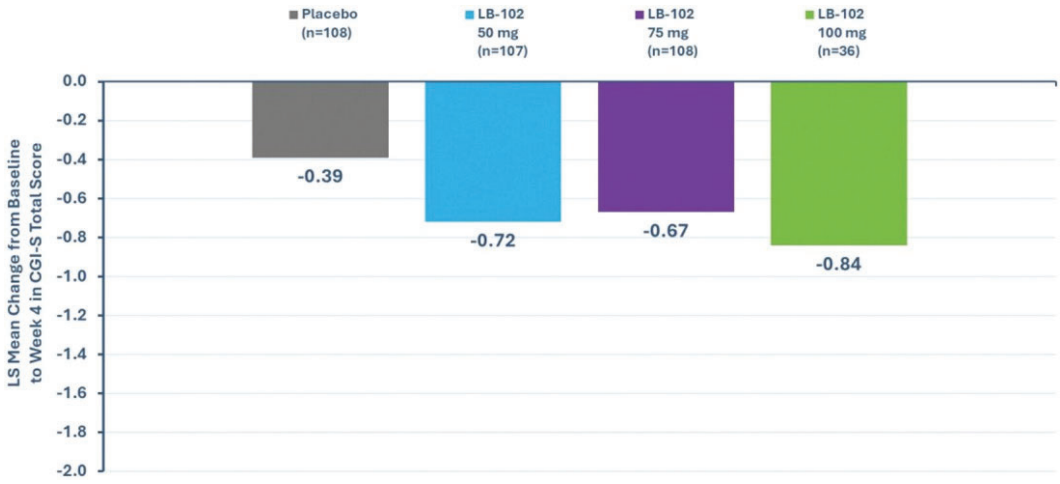
LS Mean change in PANSS total score from baseline to Week 4 in positive subscale.



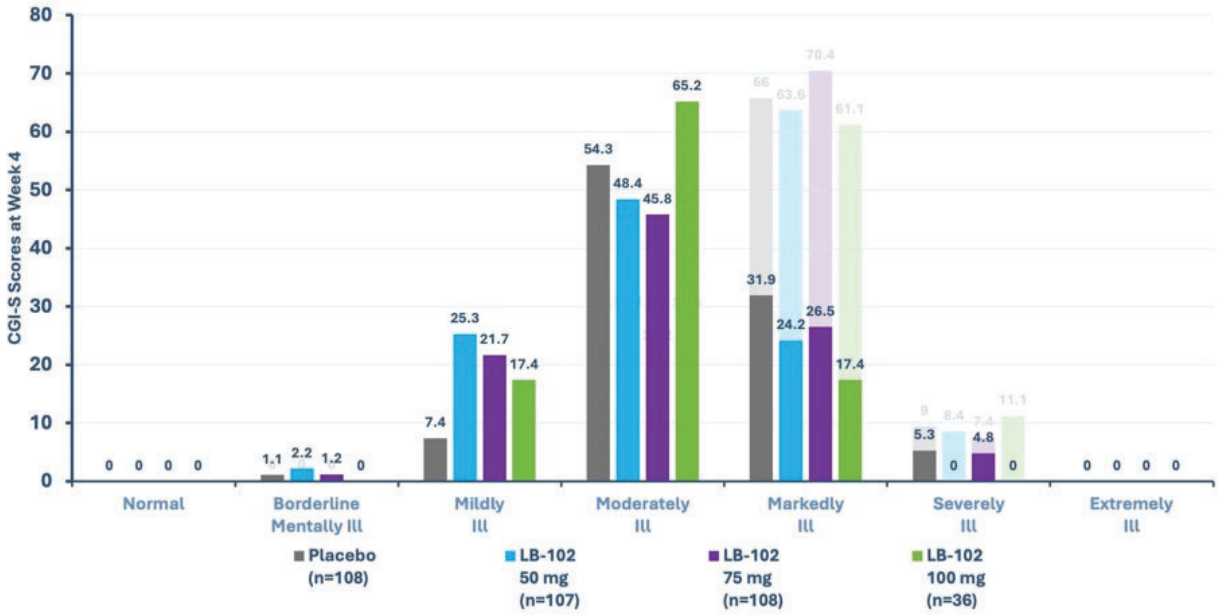
LS Mean change in PANSS score from baseline to Week 4 in negative subscale.

We also conducted an exploratory post-hoc analysis of our Phase 2 data on the treatment effect in patients with negative symptoms at baseline (i.e., those patients with a PANSS Negative Subscore greater than or equal to 24). In patients with negative symptoms at baseline, the LS Mean change in negative symptom scores at Week 4 was -1.6 (placebo), -3.4 (50 mg, Δ -1.7, p=0.0045 versus placebo; effect size=0.67), -2.6 (75 mg, Δ -1.00, p=0.1501, effect size=0.34), and -3.3 (100 mg, Δ -1.70, p=0.0658, effect size=0.60). Across all analyses, the effect on negative symptoms was seen at the first measurement at week 1 and continued through Week 4.

Using the CGI-S scale, participants in all three dose cohorts demonstrated an improvement in total scores from baseline to Week 4. We observed a 0.72-point decrease (p=0.0008), 0.67-point decrease (0.0048), and 0.84-point decrease (0.0026) in the 50 mg, 75 mg, and 100 mg dose cohorts, respectively, compared to a 0.39-point decrease in the placebo cohort. With these changes, the majority of participants shifted from markedly ill (CGI-S of 5) at baseline to moderately ill (CGI-S of 4, range of 45.8% to 65.2% of participants across all three dose cohorts) or mildly ill (CGI-S of 3, range of 17.4% to 25.3% of participants across all three dose cohorts). A small number of participants (0% to 2.2% across all three dose cohorts) achieved a CGI-S score of 2, which is considered borderline mentally ill.



LS mean change in CGI-S total score from baseline to Week 4.



Shift in CGI-S Score from baseline (shadowed colors) to Week 4 (solid colors).

We also evaluated the PANSS Marder factor, a way to analyze the PANSS data to identify responses in different dimensions of schizophrenia, including positive symptoms, disorganized thought, uncontrolled hostility/excitement, negative symptoms and anxiety/depression. PANSS Marder is a way to group the 30 individual items of the PANSS into five broader categories or dimensions. This factor structure is widely used in clinical trials and research to assess and analyze symptoms of schizophrenia. Statistically significant reductions were seen from baseline to Week 4 for all three dose cohorts for positive symptoms, disorganized thought and uncontrolled hostility/excitement. Numerical reductions, which did not reach statistical significance, were observed from baseline to Week 4 for all three dose cohorts for negative symptoms and anxiety/depression. These findings are depicted below:

*Change in PANSS Scores from baseline to Week 4 for each of the five Marder factors; * P<0.05, ** P<0.01 versus placebo.*

Safety and Tolerability Results

In the Phase 2 trial, LB-102 was generally well tolerated. Safety was assessed through TEAEs, and EPS was assessed through TEAEs as well as the Simpson-Angus Scale, or SAS, the Barnes Akathisia Rating Scale, or BARS, and the Abnormal Involuntary Movement Scale, or AIMS. The majority of TEAEs were mostly transient and mild to moderate in severity. TEAEs were defined as any adverse event that began on or after the first dose of trial medication, or any pre-existing condition that reappeared during the treatment period and up to 14 days following the last dose. TEAEs were reported in 56% (placebo), 69% (50 mg), 57% (75 mg), and 75% (100 mg) of participants. The most commonly reported TEAEs were psychiatric neurological conditions that many participants were experiencing at the time of enrollment. Weight increase was the only TEAE to occur in at least 5% of the total population and at a rate at least twice that observed with placebo (LB-102 50 mg at 12.1%; LB-102 75 mg at 7.4%; LB-102 100 mg at 8.3%; placebo at 3.7%). This TEAE includes any weight increase without a threshold. Over the course of the trial, we observed approximately 1.6 kg placebo-adjusted weight gain on a last observation carried forward basis. Despite the weight gain observed in the four-week trial, no clinically meaningful signal in metabolic parameters such as cholesterol, LDL, HDL, triglycerides or fasting glucose were observed. The discontinuation rate reached approximately 18% during the treatment period (four weeks) and approximately 27% when taking into account up to 14 days following the last dose. The most common comorbid medical conditions at baseline were insomnia (74.1%), anxiety (58.8%), headache (40.1%), depression (32.9%), and agitation (30.1%). Comorbid conditions at study entry enriched the reporting of TEAEs in our trial. Because TEAEs were defined as any adverse event that began on or after the first dose of trial medication, or any pre-existing condition that reappeared during the treatment period and up to 14 days following the last dose, the rates of certain AEs, such as insomnia, appear elevated in both placebo and LB-102 patients. Change from baseline to Week 4 in SAS, AIMS, and BARS demonstrated no difference between treatment arms and placebo and there were no reports of orthostasis among patients treated with LB-102 in the trial. The following table summarizes the adverse events from the trial:

Adverse Events	**50 mg (N=107)**	**75 mg (N=108)**	**100 mg (N=36)**	**Placebo (N=108)**
Insomnia	27 (25.2%)	23 (21.3%)	14 (38.9%)	24 (22.2%)
Headache	12 (11.2%)	9 (8.3%)	2 (5.6%)	10 (9.3%)
Anxiety	10 (9.3%)	9 (8.3%)	4 (11.1%)	9 (8.3%)
Agitation	11 (10.3%)	6 (5.6%)	4 (11.1%)	10 (9.3%)

Adverse Events	50 mg (N=107)	75 mg (N=108)	100 mg (N=36)	Placebo (N=108)
Weight increase	13 (12.1%)	8 (7.4%)	3 (8.3%)	4 (3.7%)
Hyperprolactinemia	11 (10.3%)	8 (7.4%)	6 (16.7%)	0
Blood creatine phosphokinase increased	4 (3.7%)	1 (0.9%)	2 (5.6%)	3 (2.8%)
Alanine aminotransferase increased	3 (2.8%)	1 (0.9%)	2 (5.6%)	1 (0.9%)
Somnolence	1 (0.9%)	4 (3.7%)	2 (5.6%)	0
Constipation	4 (3.7%)	1 (0.9%)	2 (5.6%)	0

TEAEs reported in 5% or more of patients in any cohort.

Ten participants reported TEAEs leading to withdrawal, including two in each of the placebo and 50 mg cohorts as well as three in each of the 75 mg and 100 mg cohorts. There were five reported serious adverse events, or SAEs, overall with two SAEs in the placebo cohort (psychotic disorder and death), one SAE in the 50 mg cohort (suicidal ideation – deemed possibly related to treatment), one SAE in the 75 mg cohort (dystonia – deemed possibly related to treatment) and one SAE in the 100 mg cohort (psychotic disorder – deemed not related to treatment). The incidence of TEAEs was similar across groups, with most events being mild or moderate.

Because of the frequency of certain adverse events associated with schizophrenia medications, we identified adverse events of special interest, such as EPS (including akathisia), sedation, adverse events associated with a prolactin increase, and QT interval corrected for heart rate, or QTcF, prolongation. These adverse events are depicted in the tables below.

EPS

	Number of subjects (% of treatment group)			
Preferred Term	**50 mg (N=107)**	**75 mg (N=108)**	**100 mg (N=36)**	**Placebo (N=108)**
Dystonia	0	3 (2.8%)	1 (2.8%)	1 (0.9%)
Akathisia	1 (0.9%)	2 (1.8%)	0	1 (0.9%)
Extrapyramidal disorder	0	1 (0.9%)	1 (2.8%)	2 (1.9%)
Total EPS	1 (1.0%)	6 (5.6%)	2 (5.6%)	4 (3.7%)

AEs Related to Prolactin Increase

	Number of subjects (% of treatment group)			
Preferred Term	**50 mg (N=107)**	**75 mg (N=108)**	**100 mg (N=36)**	**Placebo (N=108)**
Galactorrhea	2 (1.9%)	1 (0.9%)	0	0
Breast enlargement	0	0	1 (2.8%)	0
Erectile dysfunction	0	0	1 (2.8%)	0
Total related to Prolactin	2 (1.9%)	1 (0.9%)	2 (5.6%)	0

Sedation

	Number of subjects (% of treatment group)			
Preferred Term	**50 mg (N=107)**	**75 mg (N=108)**	**100 mg (N=36)**	**Placebo (N=108)**
Sedation	0	1 (0.9%)	0	0

QTcF Prolongation

	QTcF from Baseline at Day 28 (ms)			
	50 mg (N=107)	**75 mg (N=108)**	**100 mg (N=36)**	**Placebo (N=108)**
Baseline	393.4	394.7	390	393.5
Day 28	**4.9**	**4.3**	**5.4**	**1.2**

Stopping criteria were not met at any dose level.

Exploratory Endpoints

We also included a measure of cognitive performance as an exploratory endpoint in our Phase 2 trial. This analysis utilized the CogState Computerized Schizophrenia Battery of Tests, a well validated measure of cognitive ability in subjects with schizophrenia. Patients had one practice session during the screening visit and completed the actual test on the first day of treatment (Day 1), the baseline assessment, and again on the last day of treatment (Day 28), the final assessment. The CogState battery of tests utilized in our Phase 2 trial consisted of five tests designed to evaluate psychomotor function, memory, attention, working memory, and executive function. Test completion rate, one measure of quality control, was greater than or equal to 99% for each test across baseline and Day 28 visits. The test performance pass rate, another metric of quality control where data for a complete test is compared to expected rates of performance, was generally high for each test, with rates ranging from 92.4 to 99.4%. As part of our analysis of this data and consistent with other published literature utilizing the same CogState battery of tests, we conducted a post-hoc analysis in which we computed a global composite effect size, or overall improvement in cognitive performance, versus placebo. The analysis was completed in all patients who completed the planned 4 weeks of treatment and completed all scheduled cognition and PANSS assessments and did not enrich for patients with higher levels of cognitive impairment at baseline. After 4 weeks of treatment with LB-102, a robust, dose-dependent, and significant treatment effect size was identified in the completer population for all doses of LB-102 compared with placebo. Results of this analysis are highlighted in the table below.

Dose	Effect Size versus Placebo	p-value	n
50 mg	0.26	0.0476	90
75 mg	0.41	0.0027	83
100 mg	0.66	0.0018	23

A limitation of interpreting improvements in cognitive performance in the setting of treatment for acute schizophrenia is the potential that improvements in schizophrenia symptoms lead to improvements in cognitive performance. To examine the extent to which drug-related improvement in general cognitive performance was an indirect consequence of the effect of LB-102 on total schizophrenia symptoms (PANSS total score), and consistent with other therapeutics that have evaluated global cognitive performance in acute schizophrenia, we conducted a post hoc linear regression analysis comparing changes in global cognitive performance with changes in PANSS total score following treatment with LB-102. This analysis demonstrated a weak (near-zero) correlation between these measures suggesting that improvements in cognitive performance observed in our Phase 2 trial were unlikely to have been driven by improvements in schizophrenia symptoms. To further explore this, we also conducted a post-hoc mediation analysis that was designed to assess whether the improvement in cognitive performance, as measured by the Global Cognition composite score, was a direct effect of LB-102 or an indirect consequence of the effect of LB-102 on total schizophrenia symptoms. Results of the analysis demonstrated that the cognitive benefit was primarily, and statistically significantly, a direct effect of LB‑102.

We believe that the magnitude of improvement in cognitive performance observed in this trial, the dose-dependent effect, and the post hoc linear regression and mediation analyses all support the further evaluation of the potential cognitive impacts of LB-102 in schizophrenia including in patients who have been stabilized with respect to positive symptoms of the disease. We are encouraged by the improvements observed in cognitive performance in this trial and intend to further investigate the effects of LB-102 on cognition in schizophrenia, bipolar depression, and adjunctive MDD. Improvements in cognitive performance, if replicated in our subsequent clinical trials, have the potential to further support the differentiation of LB-102.

Phase 3 NOVA-2 Trial of LB-102 in Acute Schizophrenia and Planned Additional NDA-Enabling Studies

We initiated a six-week Phase 3 trial (NOVA-2) of LB-102 in participants with acute schizophrenia in March 2026, which we believe, if positive, may be sufficient to support a regulatory approval application along with our Phase 2 trial and other NDA-enabling activities. The Phase 3 trial is a three-arm, inpatient, double-blinded, placebo-controlled, oral once-daily dose of LB-102 in patients with acute schizophrenia, with a six-week treatment duration. To better inform potential future commercial use of LB-102, we are studying the effects of two doses, 50 mg LB-102 or 100 mg LB-102, versus placebo in this trial, and patients will be randomized in a 1:1:1 ratio across the three arms of the trial. All patients will start at their assigned dose level without titration. The sample size will be approximately 460 patients. We designed our Phase 3 to leverage the operational framework of our Phase 2 trial. We are conducting this trial entirely in the United

States at approximately 25 sites, a similar number of sites as were utilized in our Phase 2 acute schizophrenia trial and there is a significant overlap between the sites utilized in our Phase 2 trial and those we are utilizing in the Phase 3 trial.

The primary endpoint of the trial is change from baseline in total PANSS score at Day 42. To mitigate the risk of an elevated placebo response in this trial, we are employing the same strategies which proved effective in our Phase 2 acute schizophrenia trial including consistent, frequent, and close engagement with clinical sites, the use of two third-party vendors (including the one used in our Phase 2 trial) to help identify and exclude professional patients from the trial, and a centralized review of PANSS ratings to ensure consistency and quality control throughout the trial. Secondary endpoints include CGI-S, PANSS positive and negative subscales, Marder factor scores, the Personal and Social Performance Scale, or PSP, and cognition as well as safety and tolerability. We believe that the 6-week duration of this Phase 3 trial has the potential to further improve PANSS reductions observed following treatment with LB-102 given that in our Phase 2 trial, the PANSS score in the LB-102 treated arms declined at a faster rate than placebo through the 28-day duration of our Phase 2 trial. We expect to report topline data from the trial in the second half of 2027. Concurrently with the Phase 3 trial we expect to run an outpatient, open label trial (NOVA-3) to accrue the requisite safety population required to support NDA submission as well as other clinical and non-clinical studies typically required by FDA at the time of approval. To support approval, the safety population must include at least 1,500 cumulative patient exposures to LB-102, including at least 100 patients with greater than or equal to one year of exposure and 300 patients with greater than or equal to six months of exposure. As a result, we expect to enroll approximately 900 patients in our planned open label safety trial. If our Phase 3 trial is positive, we plan to hold a pre-NDA meeting with the FDA in the first quarter of 2028 to seek agreement from FDA on the suitability of our data to support an NDA submission for the treatment of schizophrenia with potential for submission of such NDA thereafter.

LB-102 for the Treatment of Mood Disorders: Bipolar Depression and MDD

Beyond the potential advantages in treating schizophrenia, we believe there is significant potential for LB-102 as a treatment for mood disorders.

It is widely recognized that episodes of major depression whether unipolar (as in MDD) or bipolar (as in bipolar depression) are characterized by a similar imbalance in the neurotransmitters serotonin, noradrenaline, and dopamine, regardless of the underlying pathophysiology of the disease.

Based on existing third-party data investigating amisulpride and a non-racemic form of the drug as a treatment for several types of depression, including bipolar depression, and the approval of amisulpride in multiple countries outside of the United States for the treatment of dysthymia, a form of persistent depression, we have identified bipolar depression and adjunctive treatment for MDD as our next development opportunities for LB-102.

We believe LB-102's strong and selective antagonism of the D_2, D_3, and 5HT7 receptors makes it well suited for treating bipolar depression, providing potential control of psychosis and mania through its effects on D_2 and potential for antidepressive and pro-cognitive effects through its antagonism of 5HT7 and D_3. This receptor binding profile also supports the development of LB-102 as a potential treatment for adjunctive MDD. Moreover, at low doses, LB-102 and amisulpride have selectivity for pre-synaptic autoreceptors that serves to increase dopamine signaling which is underactive in depression. We believe this mechanistic profile supports the potential for efficacy for both depressive and residual symptoms such as anhedonia and cognitive impairment, which remain key unmet needs in the treatment of both bipolar depression and MDD.

Results from our Phase 2 trial of LB-102 in acute schizophrenia further support the potential differentiation of LB-102 in bipolar depression and adjunctive MDD where burdensome side effects and residual symptoms of anhedonia and cognitive impairment remain significant unmet needs. In this trial, LB-102 demonstrated strong antipsychotic activity, robust effects on negative symptoms and cognitive performance and a favorable tolerability profile, characterized by low rates of EPS (including akathisia), minimal sedation, and few gastrointestinal side effects.

Amisulpride is approved for the treatment of dysthymia, a form of depression, in certain countries outside of the United States and has been shown to be as effective as certain approved agents for MDD and dysthymia. We believe that results in dysthymia and MDD provide strong scientific and clinical rationale for development of LB-102 in the treatment of depressive episodes associated with bipolar disorder or bipolar depression as well as adjunctive MDD.

Additionally, among the five antipsychotics currently approved for schizophrenia and MDD or treatment resistant depression that were also studied in late-stage bipolar depression trials (quetiapine, cariprazine, aripiprazole, lumateperone, and olanzapine), four out of five, or 80%, generated positive data for the treatment of bipolar depression. There is also widespread use of amisulpride in mood disorders, with approximately 20% of the at least two million monthly prescriptions in Europe written for mood disorder indications, with approximately 3.4% of prescriptions in Europe written for bipolar disorder and 16.2% for depression.

A non-racemic form of amisulpride showed strong antidepressant activity in two independent third-party, placebo-controlled bipolar depression trials with an approximately 17 to 18-point reduction in MADRS from baseline observed in each trial. The non-racemic form of amisulpride has been shown to be substantially similar to amisulpride in preclinical models. We believe that the approval of amisulpride in the United Kingdom for the treatment of psychosis and mania serves as additional supportive evidence for the broader utility of LB-102 to treat neuropsychiatric disorders such as bipolar depression.

Our ongoing Phase 2 trial for bipolar depression is designed to compare a fixed-flexible dose of LB-102 with placebo. This trial design allows us to evaluate two doses of LB-102 in one arm of the trial, thereby increasing the chances for a patient to derive clinical benefit from treatment with LB-102, while retaining the advantages of a two-arm trial, which is known to mitigate the risk of a high placebo rate. Flexible dose trials typically have better signal detection than fixed dose trials for depression. A third-party study from 2003 examined if the dosing schedule (either a fixed dose or a flexible dose), in an antidepressant clinical trial affects the frequency with which antidepressants show statistical superiority over placebo. In flexible dose trials, 59.6% (34/57) of the antidepressant treatment arms were statistically significant compared to placebo. In contrast, in the fixed dose trials, only 31.4% (11/35) of the antidepressant treatment arms were statistically significant compared to placebo. These data suggest a significantly lower magnitude of symptom reduction with placebo in flexible dose trials compared to fixed dose trials.

We believe LB-102 has the potential to provide improved tolerability and clinical activity in bipolar depression and adjunctive MDD compared to currently available treatments worldwide, which are associated with troubling adverse events and insufficient efficacy for certain symptoms, including anhedonia and cognitive impairment associated with the diseases.

Bipolar Depression

Overview and Disease Background

People living with bipolar depression experience extreme shifts in mood, energy, and behavior, alternating between manic and depressive states. There are two types of bipolar disorder, distinguished as bipolar 1 and 2, which are characterized by chronically occurring episodes of mania or hypomania alternating with depression. To be diagnosed with bipolar 1 disorder, a person must experience a manic episode defined as a distinct period of persistently elevated or irritable mood with increased activity or energy lasting for at least seven days or requiring hospitalization. The manic episode may be preceded or followed by a hypomanic or major depressive episode. A bipolar 2 disorder diagnosis is based on experiencing hypomanic episode and major depressive episode without a manic episode. Manic episodes are markedly more severe than hypomanic episodes.

People experiencing a manic episode may have a highly inflated sense of self-worth or self-esteem, talk quickly and rapidly shift from one idea to the next, have trouble concentrating, be easily distracted, have a decreased need for sleep, engage in reckless or risk-taking behavior and have a fixed or mistaken grandiose or persecutory belief. During a depressive episode, a person may experience poor concentration, feelings of excessive guilt or low self-worth, hopelessness about the future, thoughts of dying or suicide, disrupted sleep, changes in appetite or weight and feeling very tired or low in energy. Approximately 60% of patients with bipolar depression have cognitive deficits or anhedonia. For those living with bipolar disorder, an estimated 82.9% have serious impairment due to the disease, the highest percent of serious impairment among all mood disorders, indicating there is significant need for new and better treatment options.

Limitations of Current Treatments for Bipolar Depression

Worldwide, it is estimated that 40 million people live with bipolar disorder. In the United States, an estimated 2.8%, or approximately seven million people, experience bipolar disorder in a given year. Stigma and discrimination against

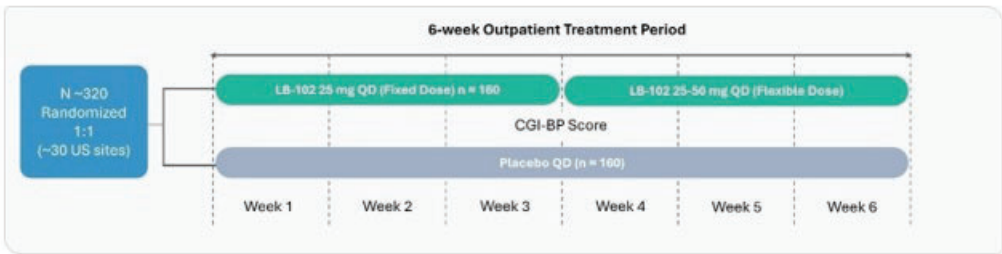
people with bipolar disorder are widespread, which can undermine access to treatment. Although with proper treatment, recovery is possible. Mood stabilizers and antipsychotic drugs which are the mainstay for treatment of bipolar disorder, have been shown to help manage periods of acute mania as well as depression. Based on third-party market research conducted for us, an important advantage of certain antipsychotic drugs in the treatment of bipolar depression is the ability to control depressive symptoms while preventing the emergence of mania. Antidepressants, such as selective serotonin reuptake inhibitors, can be effective in controlling depressive symptoms but also carry a risk of triggering manic events and therefore are typically reserved for later lines of therapy. This market research, together with an advisory board that we held, also highlight unmet needs in the treatment of bipolar depression in areas of anhedonia and cognition. These unmet needs include fewer adverse events, better efficacy, including improvements in cognition and anhedonia, improved compliance to treatment, and a desire for therapies with novel mechanisms of action. Bipolar depression patients have higher baseline levels of function than schizophrenia patients and as a result the adverse events such as EPS and sedation which are commonly associated with current approved therapeutics can be particularly challenging for these patients.

Phase 2 ILLUMINATE-1 Trial of LB-102 in Bipolar 1 Depression

We initiated a Phase 2 trial (ILLUMINATE-1) of LB-102 in participants with depressive episodes associated with bipolar 1 disorder or bipolar depression in February of 2026, which we believe, if positive, could potentially support a regulatory approval for the treatment of bipolar depression as a monotherapy along with an additional Phase 3 trial. We plan to report topline data for this trial in the first quarter of 2028 and, subject to positive results from the trial, meet with the FDA to discuss trial results at an end-of-Phase 2 meeting thereafter. The Phase 2 trial is an outpatient, two-arm, double-blinded, placebo-controlled trial, testing an oral, once-daily fixed-flexible dose of LB-102 in patients with depressive episodes associated with bipolar 1 disorder, with six-week treatment duration. We plan to enroll approximately 320 patients and conduct this trial entirely in the United States at approximately 30 sites. Patients are being randomized in a 1:1 ratio to LB-102 or placebo.

Across most atypical antipsychotics, bipolar depression doses are usually approximately 50% lower than schizophrenia doses to keep D_2 receptor occupancy at a level that lowers the potential for EPS (including akathisia) yet high enough for antidepressant benefit. This is the dosing model that was used by Vraylar and Latuda, both of which are approved for schizophrenia and bipolar depression. In contrast, Caplyta, another drug approved for use in both schizophrenia and bipolar depression, utilized the same dose in both indications, in part because of its low rates of EPS. In selecting doses for our Phase 2 trial, we are blending these two paradigms. We are initiating all patients on half the lowest dose used in our acute schizophrenia trial (25 mg). Importantly, we believe that results of our Phase 2 schizophrenia trial, which demonstrated <1% EPS (including akathisia) and no sedation or orthostasis even at 50 mg, provide us an opportunity to explore that dose in bipolar depression. This is similar to Caplyta, which obtained approval for a single dose across both indications.

Our Phase 2 ILLUMINATE-1 trial design of LB-102 in bipolar 1 depression is as follows:



As shown above in our Phase 2 trial, all patients randomized to receive LB-102 are beginning treatment at 25 mg for the first three weeks of the trial. At the end of Week 3, if a patient has not improved based on a protocol guided set of specific items in the Clinical Global Impression-Bipolar Illness, or CGI-BP, scale and the patient is tolerating the drug, the dose of LB-102 will be increased in this patient to 50 mg for the remaining three weeks of the trial, subject to an allowance for up to one dose reduction for safety reasons. This trial design allows us to evaluate two doses of LB-102 in a single arm of the trial, thereby increasing the chances for a patient to derive clinical benefit from treatment with LB-102, while retaining the advantages of a two-arm trial, which is known to mitigate the risk of a high placebo rate. The primary endpoint is MADRS-10 and will compare all LB-102 treated patients regardless of the dose received versus placebo. Secondary endpoints will include MADRS-6, CGI-BP-S, cognitive performance, anhedonia, as well as safety and tolerability, utilizing specific scales dedicated to the measurement of anhedonia and cognitive performance. We have

designed this trial to highlight what we believe will be differentiating attributes of LB-102 in bipolar depression. Specifically, we are targeting competitive MADRS-10 versus other approved agents, improved tolerability as evidenced by lower rates of sedation and gastrointestinal side effects compared with other approved agents, a rate of EPS (including akathisia) consistent with what we observed in our schizophrenia Phase 2 trial, and the potential to demonstrate improvements in anhedonia and cognition versus placebo, which we believe could address important unmet needs in this disease.

Flexible dose trials typically have better signal detection than fixed dose trials for depression. A third-party study from 2003 examined if the dosing schedule (either a fixed dose or a flexible dose), in an antidepressant clinical trial affects the frequency with which antidepressants show statistical superiority over placebo. In flexible dose trials, 59.6% (34/57) of the antidepressant treatment arms were statistically significant compared to placebo. In contrast, in the fixed dose trials, only 31.4% (11/35) of the antidepressant treatment arms were statistically significant compared to placebo. These data suggest a significantly lower magnitude of symptom reduction with placebo in flexible dose trials compared to fixed dose trials. To further reduce the potential for an elevated placebo rate, we are employing many of the same strategies which proved effective in our Phase 2 acute schizophrenia trial including consistent, frequent, and close engagement with clinical sites, the use of two third-party vendors (including the one used in our Phase 2 trial) to help identify and exclude professional patients from the trial, and a centralized review of MADRS ratings to ensure consistency and quality control throughout the trial. We are also utilizing remote structured assessments to enhance enrollment precision in our clinical trial, which has been shown to reduce placebo response rates.

Following a successful Phase 2 trial, we believe that a single additional Phase 3 trial could support an approval for LB-102 as a monotherapy to treat bipolar depression. We expect an additional Phase 3 trial to be required to support approval as an adjunctive therapy for bipolar depression. Following a successful Phase 2 trial, we may also consider conducting two Phase 3 trials in bipolar depression, one as a monotherapy and one as an adjunctive therapy in combination with mood stabilizers, a commonly used treatment for bipolar depression. Based on historical precedent, we expect to be able to utilize the safety dataset that we generate from clinical trials across all indications to support a potential approval for LB-102 in bipolar depression as the doses utilized in our bipolar depression trial will be similar to those utilized in our other clinical trials. As a result, the ability to leverage the safety data set generated as part of the schizophrenia development program has potential to streamline the cost and timeline to approval for bipolar depression.

Major Depressive Disorder

Overview and Disease Background

MDD is a common and serious mood disorder and the leading cause of disability worldwide, impacting 280 million people globally and approximately 20 million people in the United States. MDD is characterized by persistent depressed mood and loss of interest. It can significantly impair how individuals feel, think and behave, with substantial impacts on daily functioning and quality of life. While some patients achieve an initial or adequate response with currently available therapies, a large proportion experience clinically meaningful residual symptoms and tolerability limitations.

MDD can lead to lost work productivity and increased morbidity and mortality due to direct effects (e.g., increased risk of suicide, reduced functional behaviors and interpersonal relationships) and indirect effects (e.g., increased prevalence of diabetes) of the disease. Over 10 million people in the U.S. reported experiencing a MDD episode with “severe impairment” that resulted in an inability to manage to home, work, have relationships with others or have a social life

Limitations of Current Treatments for MDD

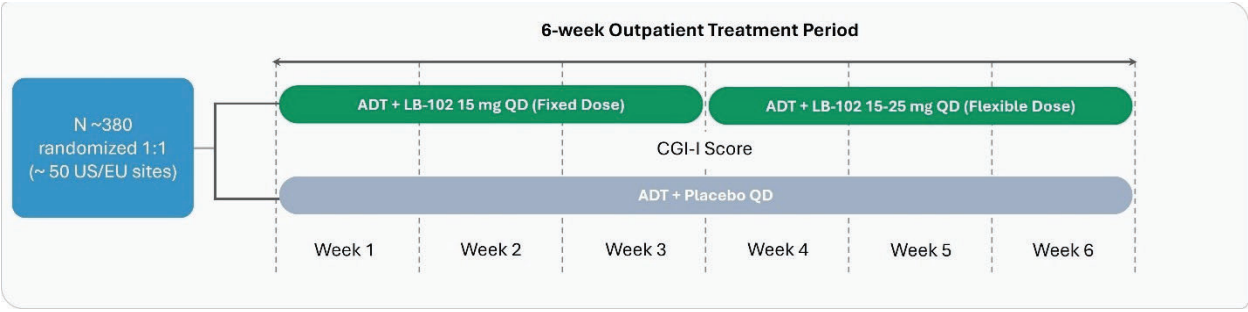
With currently available treatments, approximately 60% of patients experience two or more residual symptoms and 45%-70% experience cognitive dysfunction and/or anhedonia. It is estimated that of the approximately 20 million adults in the U.S. that have been diagnosed with MDD, approximately 60%, or approximately 12 million receive drug therapy. While some patients achieve an initial or adequate response with currently available therapies, a large proportion experience clinically meaningful residual symptoms and tolerability limitations. With currently available treatments, approximately 60% of patients experience two or more residual symptoms and 45%-70% experience cognitive dysfunction and/or anhedonia (e.g., reduced capacity to experience pleasure or interest in previously enjoyed activities). For patients with inadequate response to therapy, a second medication is frequently added to the existing medication regime, often targeting complementary neurochemical pathways with a goal of achieving broader and more durable symptom control. Of the 12 million patients receiving drug therapy, approximately 50% require second-line treatment, with 70%

of that group requiring third-line treatment. With approximately six million patients requiring second-line treatment and four million requiring third-line treatment, there is a large addressable patient population whose needs are not met by the currently available therapies.

Phase 2 Trial of LB-102 in Adjunctive MDD

We intend to initiate a Phase 2 clinical trial of LB-102 as an adjunctive treatment MDD. The planned Phase 2 trial is expected to be a multi-center, randomized, double-blind, placebo-controlled trial with fixed- and flexible-doses and is designed to evaluate the efficacy and safety of two doses of LB-102 (15 mg and 25 mg given once daily) for the treatment of patients with MDD experiencing inadequate response after 1-2 prior trials with standard antidepressant therapy.

Our Phase 2 trial design of LB-102 in adjunctive MDD is as follows:



The two-arm, six-week, outpatient trial is expected to enroll approximately 380 patients with MDD at approximately 50 sites in the U.S. and Europe. Patients will be randomized 1:1 to receive either LB-102 or placebo in addition to standard antidepressant therapy. The primary endpoint is the Montgomery–Åsberg Depression Rating Scale (MADRS)-10 at week six. The primary statistical analysis will compare results from all patients receiving LB-102, regardless of dose, with placebo. Secondary endpoints include Clinical Global Impression-Improvement/Clinical Global Impression-Severity, anhedonia, function, cognition, safety and tolerability.

The Company believes LB-102 has potential for a favorable benefit–risk profile as an adjunctive treatment for major depressive disorder as compared to currently available antipsychotic therapies based on its strong mechanistic rationale, validating clinical and real-world experience with amisulpride and supportive results from its previously completed Phase 2 schizophrenia trial. We plan to initiate this trial in early 2027 and expect to report topline data in the first half of 2029.

Future Development Opportunities of LB-102

Potential Additional Indications for LB-102

In addition to schizophrenia, bipolar depression and adjunctive MDD, we are exploring the possibility of testing LB-102 in other neuropsychiatric disorders such as predominantly negative symptoms of schizophrenia, Alzheimer's disease psychosis and agitation, as well as other neuropsychiatric diseases

We are assessing LB-102 as a potential treatment for psychosis and agitation in Alzheimer's disease. A third-party clinical trial published in 2018 in The Lancet studying the efficacy of amisulpride in treating elderly patients with very late-onset schizophrenia-like psychosis showed that over 12 weeks, there was a statistically significant 7.7-point improvement in the BPRS (Brief Psychiatric Rating Scale, a prior iteration of the PANSS) for amisulpride as compared to placebo. Importantly, amisulpride was well-tolerated in this vulnerable elderly population, where the average age in this trial was 81. Another third-party clinical trial, published in 2017, explored dose levels of off-label use of amisulpride in treating older people with Alzheimer's disease-related psychosis. The clinical trial showed a reduction in symptoms was associated with amisulpride concentration and D_2/D_3 occupancy. To further investigate the potential of LB-102 in Alzheimer's disease, we will need to conduct a Phase 1 trial to evaluate the pharmacokinetics and safety of LB-102 in a healthy elderly population (aged 65 and older). It is estimated that approximately 40% of the approximately seven million Americans with Alzheimer's disease experience psychosis or agitation.

While our current schizophrenia clinical program is designed to investigate LB-102 as a treatment for people experiencing the acute phase, or positive symptoms, of schizophrenia, we believe LB-102 also has potential to address predominantly negative symptoms based on the results from our Phase 2 trial and clinical experience to date with amisulpride, an indication with significantly fewer treatment options. Amisulpride demonstrated a statistically significant benefit versus placebo in three independent third-party placebo-controlled trials in patients with predominantly negative symptoms with treatment durations ranging from six weeks to six months. We are also encouraged by the magnitude of improvement in cognitive performance we have observed to date in our schizophrenia trials and are also assessing the potential to study LB-102 as a treatment for cognitive impairment of schizophrenia, an indication for which there are no approved therapies. In both negative symptoms of schizophrenia and CIAS, we will need to study LB-102 in patients who have been stabilized with respect to the positive symptoms of their disease.

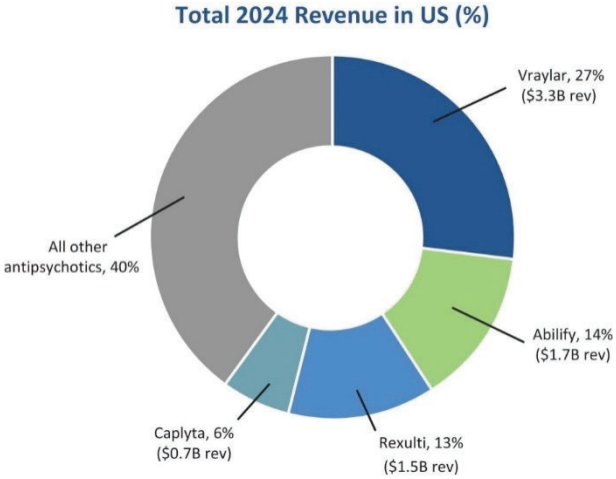
Potential New Formulations of LB-102

We are also developing an LAI formulation of LB-102, which may improve treatment adherence, a common issue in patients with schizophrenia and bipolar disorder. LB-102's consistent dopamine receptor engagement over 24 hours and the lower administered dose may allow LB-102 to be administered as an LAI. We believe an effective LAI form of LB-102 has the potential to benefit patients worldwide, as relatively few approved agents are available as long-acting formulations. The American Psychiatric Association recommends injectable formulations in circumstances where doing so will improve adherence, decrease mortality, reduce hospitalization risk, and decrease treatment discontinuation rates.

We believe LAI formulations can have additional benefits in treating symptoms of schizophrenia, such as consistent drug exposure, which is potentially beneficial compared to orally dosed antipsychotic drugs, as it relieves the requirement for patients or their care partners to rely on often self-enforced daily oral dosing to maintain efficacy. The latest guidance from the American Psychiatric Association calls for the use of LAI with patients who have a history of poor adherence. Using LAI antipsychotic drugs to treat schizophrenia patients may decrease mortality risk, reduce hospitalization risk, and decrease rates of treatment discontinuation. We believe such a formulation of LB-102 would potentially benefit patients both in the United States and globally. We have commenced LAI formulation development and expect to continue these efforts in 2026. We believe that the success of the 50 mg dose in our Phase 2 acute schizophrenia trial affords the opportunity to develop an LAI.

Market Opportunity

The United States market for branded antipsychotic drugs in 2024 was approximately $12 billion, where despite the widespread use of generic drugs, several branded antipsychotic drugs each generate sales in excess of $1 billion per year. The chart below depicts the market share of branded antipsychotic drugs in the United States for 2024 in terms of revenue.

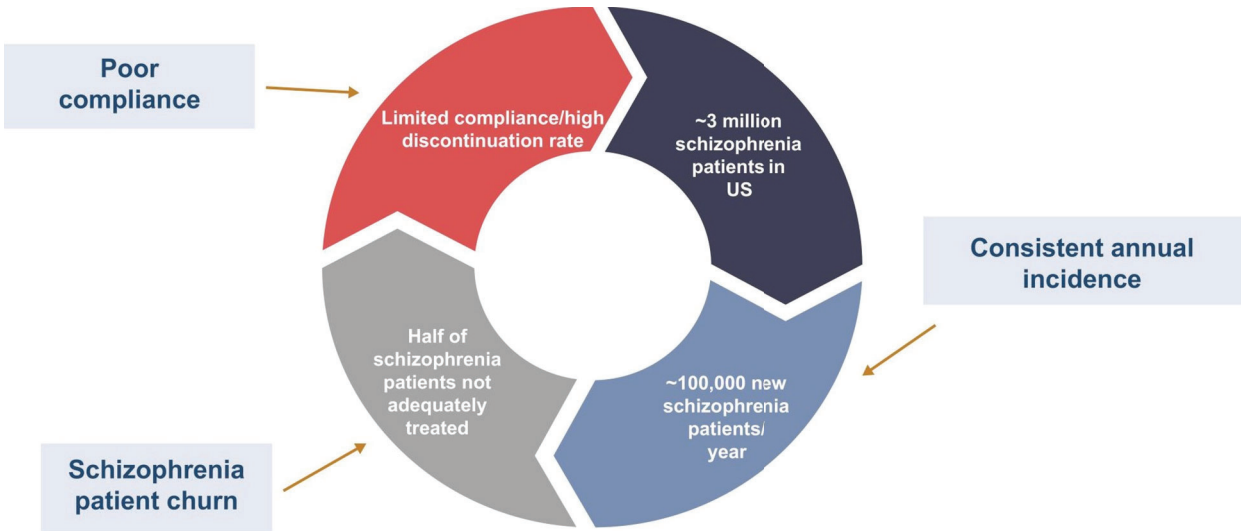


United States market for branded antipsychotic drugs – 2024.

Among the schizophrenia drugs with greater than $1 billion in sales, all have approvals in additional indications beyond schizophrenia, such as mood disorders. In addition, these drugs generally received their initial approval in schizophrenia

prior to their approvals in mood disorders. It is well recognized that in the United States, antipsychotic drugs have higher prices than antidepressants, such as the selective serotonin reuptake inhibitors. Vraylar, Abilify, Rexulti, and Caplyta are approved in the United States for the treatment of schizophrenia and adjunctive MDD in adults. Beyond schizophrenia and MDD, Vraylar, and Caplyta are approved for the treatment of bipolar depression.

The high incidence of schizophrenia, inadequate clinical response, and side effects from current therapeutics lead to a discontinuation rate of 74% within 18 months of treatment and present a clear market opportunity for more effective schizophrenia drugs that are well-tolerated. Switching treatment is also common in bipolar depression. For example, market research that we conducted suggests that approximately 61% of bipolar depression patients have switched therapies at least once.



Several factors, including new diagnoses, inadequate responses, and high discontinuation rates contribute to a significant market opportunity for effective schizophrenia drugs.

Additionally, data from 2023 show that despite limited marketing efforts, there were at least two million monthly prescriptions per year for amisulpride in the European Union. We believe that amisulpride's continued use as an agent for the treatment of schizophrenia outside of the United States over the past 25 years supports the significant commercial potential of LB-102, if approved.

License and Other Agreements

Royalty Agreements

In July 2016, we entered into several Royalty Participation Agreements, or the Original Royalty Agreements, with certain of our existing investors, co-founders, former and current directors, and former and current executive officers, including Zachary Prensky, Andrew Vaino, Ph.D., and Marc Panoff, for royalties payable, in the aggregate, of up to 5.0% of future commercial worldwide sales of LB-102. In this transaction, we received $0.2 million in cash in exchange for the certificate holders receiving convertible notes with a face value of $0.2 million, shares of our common stock and the future royalties provided for in the Original Royalty Agreements. The future royalty payments provided for in the Original Royalty Agreements had an expiration date of December 31, 2037. The royalties were transferable upon surrender of the royalty certificate accompanied by written and notarized instructions of the transfer, provided that the certificate holder could not transfer to any individual or entity (i) to which it was unlawful for us to make such payments or (ii) that owned, controlled or possessed voting rights in the aggregate of more than 10% of our common stock. We had the option to purchase all issued and outstanding royalty certificates under the Original Royalty Agreements by way of a tender offer to all such holders, which would become binding at such time as the holders of two-thirds of all outstanding royalty interests agreed in writing to accept such tender offer.

In August 2023, contemporaneously with the closing of the Series C financing, we entered into several Amended and Restated Royalty Agreements to remove the expiration date and modify royalties payable to certificate holders in the

aggregate amount of up to 2.75% of net sales of LB-102 through December 31, 2035 and increasing to up to 3.25% of net sales in 2036 and thereafter. Net sales are defined in these agreements as the gross payments received on total commercial sales of LB-102 less certain standard deductions, whether received by us or any licensee of LB-102. None of the proceeds from the Series C financing were allocated to the certificate holders as the investors in the Series C financing are not parties to the Original Royalty Agreements or the Amended and Restated Royalty Agreements. Each certificate holder has the same rights and obligations as the other holders except with respect to its individual royalty amount that may come due from us if we generate any revenue from future sales of LB-102. The certificate holders may not transfer rights under the applicable Amended and Restated Royalty Agreement to any individual, entity, corporation, partnership or any other such organization without our written consent, which shall not be unreasonably withheld. We may purchase all issued and outstanding royalty certificates under the Amended and Restated Royalty Agreements by way of a tender offer to all such holders, which will become binding at such time as the holders of two-thirds of all outstanding royalty interests thereunder agree in writing to accept such tender offer.

Intellectual Property

Overview

We strive to protect and enhance the proprietary technology, inventions and improvements that are commercially important to our business, including by seeking, maintaining, enforcing and defending patent rights. Our policy is to seek to protect our proprietary position by, among other methods, filing patent applications in the United States and in jurisdictions outside of the United States related to our proprietary technology, inventions, improvements, and product candidate that are important to the development and implementation of our business. We also rely, in part, on trade secrets and know-how relating to our proprietary technology and product candidate, continuing innovation, and in-licensing opportunities to develop, strengthen and maintain our proprietary position in the field of precision psychiatry and neuropsychiatric drug development; however, trade secrets are difficult to protect and provide us with only limited protection. Our commercial success will depend in part on our ability to obtain and maintain patent and other proprietary protection for our technology, inventions and improvements, to preserve the confidentiality of our trade secrets, and defend and enforce our proprietary rights, including any patents that we own or may obtain in the future. Intellectual property rights may not address all potential threats to our competitive advantage.

As of March 1, 2026, we owned approximately 51 patents and pending patent applications in the United States and foreign jurisdictions, including seven issued U.S. patents and 14 issued foreign patents. The issued patents, or patents that may be issued from the pending patent applications, are expected to expire between 2037 and 2047, without taking into account potentially available patent term adjustments or extensions in the United States and other countries, and assuming payment of all appropriate maintenance, renewal, and annuity fees. We expect the patent term adjustment or extension to be up to five years. Forty-three of the patents and pending patent applications relate directly to LB-102. Additionally, we own two U.S. patents that are directed to open-ring derivative compounds of LB-102. The two U.S. patents claim open-ring derivative compounds of LB-102 as compositions of matter and methods of using these derivative compounds in the treatment of schizophrenia and other mental illnesses. In addition, there are two patent applications pending in Hong Kong, one patent issued in China, and one patent application pending in China, the European patent office, and Taiwan, respectively, that are directed to uses of the R-enantiomer of LB-102. These patent applications cover methods of using the R-enantiomer of LB-102 in treating schizophrenia and other mental illnesses, such as depression, bipolar disorder, Tourette's syndrome, schizoaffective disorder, Parkinson's psychosis, Alzheimer's psychosis, oppositional defiant disorder, personality disorder, childhood schizophrenia, dysthymia, treatment resistant schizophrenia, chronic fatigue syndrome, and predominantly negative symptoms of schizophrenia.

Product Candidate Patent Portfolio

LB-102

As of March 1, 2026, we owned approximately 43 patents and pending patent applications in the United States and foreign jurisdictions relating to LB-102, including five issued U.S. patents and thirteen issued foreign patents, three pending U.S. patent applications, twenty pending foreign applications, and two pending Patent Cooperation Treaty, or PCT, applications.

We own all of the following patents and pending patent applications directed to LB-102, which are summarized below:

Indication(s)	Subject Matter	Projected Expiration Date*	Issued or Pending Patent Applications/ Jurisdiction
Schizophrenia and other mental illnesses	Composition of Matter and Method of Treatment	2037	Respectively, one patent issued in each of the following: Australia, Brazil, EPO, Indonesia, Japan, Republic of Korea, and Singapore, two patents issued in China, Hong Kong, and Malaysia, and five patents issued in the United States; one patent application pending in each of the following: Australia, Brazil, Malaysia, New Zealand, and the United States; and two patent applications pending in Singapore.
	Method of Treatment	2042	Respectively, one patent application pending in each of the following: Australia, Brazil, Canada, China, EPO, Japan, Republic of Korea, Malaysia, New Zealand, Singapore, and the United States; and two patent applications pending in Hong Kong
	Method of Treatment (Poor Cognition)	2044	One PCT application pending; and one application pending in Taiwan.
	Method of Treatment	2046	One PCT application pending; one patent application pending in Taiwan; and one provisional application pending in the United States.
	Composition of Matter	2047	One provisional patent application pending in the United States

* Projected expiration dates are based on issued patents or patents that may be issued from pending patent applications, and do not take into account possible patent term adjustments, extensions, or terminal disclaimers and assumes payment of all appropriate maintenance, renewal, and annuity fees.

With respect to LB-102, our U.S. and foreign patents and pending patent applications cover claims directed to composition of matter, and method of treating schizophrenia and other mental illnesses such as depression, bipolar disorder, Tourette's syndrome, schizoaffective disorder, Parkinson's psychosis, Alzheimer's psychosis, oppositional defiant disorder, personality disorder, childhood schizophrenia, dysthymia, resistant schizophrenia, and chronic fatigue syndrome. The issued patents covering the composition of matter of LB-102 and method of treating schizophrenia are expected to expire in 2037, and any patents that may be issued from the pending patent applications are expected to expire between 2037 and 2047, in each case, without taking into account any possible patent term adjustment or extensions or terminal disclaimers and assuming payment of all appropriate maintenance, renewal, and annuity fees. Our foreign patents and pending patent applications are filed in foreign jurisdictions including Australia, Brazil, Canada, China, Europe, Hong Kong, Indonesia, Japan, the Republic of Korea, Malaysia, New Zealand, Singapore, and Taiwan.

Intellectual Property Protection

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

covering such approved products. In the United States, the term of a patent that covers an FDA-approved drug may also be eligible for a patent term extension of up to five years under the Hatch-Waxman Act, which is designed to compensate for the period of the patent term lost during the FDA regulatory review process. The length of the patent term extension is calculated based on the length of time it takes for regulatory review. There are specific limitations to a patent term extension under the Hatch-Waxman Act. The extension cannot exceed the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent applicable to an approved drug may be extended and only those patents with claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. A patent term extension provided for under the Hatch-Waxman Act is available only for the first approved use of the drug, and thus, no extension is available if a product is approved for a subsequent use. Moreover, a patent can only be extended once, and thus, if a single patent is applicable to multiple products, it can only be extended based on one product. Similar provisions are available in Europe and certain other foreign jurisdictions to extend the term of a patent that covers an approved drug.

We intend to pursue, in the normal course of business and when possible, additional patent protection for future compositions including solid state forms, methods of use, processes, composition, method of use, process, dosing, and formulations of our product candidate(s) we develop and commercialize. We may also pursue patent protection with respect to manufacturing and other technologies. To expand market exclusivity, we intend to strategically obtain or license additional intellectual property related to a current or contemplated product candidate.

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

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

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

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

Sales, Marketing, and Commercialization

While we have hired a Chief Commercial Officer to lead the development of our commercial strategy, we do not currently have a commercial organization for the marketing, sales, market access and distribution of prescription pharmaceutical products. We intend to build our global commercialization capabilities internally over time, such that we are able to commercialize any product candidate for which we may obtain regulatory approval. We expect to manage future sales, marketing, market access and distribution through internal resources and third-party relationships. In addition, we will opportunistically explore commercialization partnerships, particularly with entities that have strong capabilities in geographies outside of the United States. As our current and future product candidates progress through clinical development and regulatory review, our commercial plans may change. Clinical data, the size of the development programs, the size of our target markets, the size of the requisite commercial infrastructure, the competitive landscape, and manufacturing needs may all influence our future commercialization strategies.

Manufacturing

We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We have engaged, and expect to continue to rely on, well-established third-party Contract Development and Manufacturing Organizations, or CDMOs, to produce and supply our product candidates for use in our preclinical studies and clinical trials. Because we are responsible for ensuring all aspects of our product candidates' compliance and quality but rely on third-party contract manufacturers and analytical testing laboratories, we must employ personnel with extensive technical, manufacturing, analytical, and quality experience to oversee our contract manufacturing and testing activities, and to compile manufacturing and quality information for our regulatory submissions. We believe our current manufacturers have the scale, systems, and experience to supply our currently planned clinical trials.

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

To adequately meet our projected commercial manufacturing needs, our CDMOs will need to scale-up production, or we will need to secure additional suppliers. Processes for producing drug substances and drug product for commercial supply must be developed, with the goal of achieving reliable, reproducible, and cost-effective production. We believe the drug substance and drug product processes for our current product candidates can be appropriately scaled.

Competition

The biopharmaceutical industry is characterized by rapid innovation and intense competition. While we believe that our lead product candidate, LB-102, offers a potentially attractive alternative to generic and branded therapeutics treating neuropsychiatric diseases, should it be approved for marketing, today we face competition from multiple biopharmaceutical and biotechnology companies that are similarly working to develop therapeutics targeting schizophrenia, as well as from academic institutions, governmental agencies, and public and private research institutions. Many of our potential competitors, either alone or with collaboration partners, have significantly greater financial resources than we do, as well as equal or greater experience in the discovery and development of product candidates, obtaining FDA and other regulatory approvals of products, and the commercialization of those products. Accordingly, our potential competitors may be more successful than we are in achieving regulatory approvals and commercializing their neuropsychiatric products. We anticipate that we will face intense and increasing competition from existing, approved drugs, if LB-102 becomes a commercial product, as well as new drugs entering the market in the future and emerging technologies that become available.

We believe the key competitive factors affecting the success of our product candidate, LB-102, that we are developing to address schizophrenia, bipolar depression, and adjunctive MDD, if approved, are likely to be efficacy, safety, frequency of dosing, convenience, price, the level of generic competition, and the availability of reimbursement from government and other third-party payors.

Patients with schizophrenia have historically been treated with a variety of antipsychotic drugs and, accordingly, we believe LB-102, if approved, would compete with several currently approved therapeutics, including: clozapine (marketed by HLS Therapeutics, Inc.); quetiapine (marketed by AstraZeneca plc); aripiprazole (marketed by Otsuka Pharmaceutical Co. Ltd.); risperidone (marketed by Janssen Pharmaceuticals, Inc.); olanzapine (marketed by Eli Lilly & Company Ltd.); haloperidol (marketed by Janssen Pharmaceuticals, Inc.); Latuda (marketed by Sumitomo Pharma America, Inc.); Invega (marketed by Janssen Pharmaceuticals, Inc.); Rexulti (marketed by Otsuka Pharmaceutical Co. Ltd and H. Lundbeck A/S); Vraylar (marketed by AbbVie Inc.); Caplyta (marketed by Janssen Pharmaceuticals, Inc.); iloperidone (marketed by Vanda Pharmaceuticals Inc.); Uzedy (marketed by Teva Pharmaceutical Industries Limited); Lybalvi (marketed by Alkermes, Inc.); and Cobenfy (marketed by Bristol-Myers Squibb Company, Inc.). We are also aware of several companies developing compounds for the treatment of schizophrenia, including Alto Neuroscience Inc., Minerva Neurosciences, Inc., MapLight Therapeutics, Inc., Neurocrine Biosciences, Inc., Reviva Pharmaceuticals Holdings, Inc., and Acadia Pharmaceuticals Inc., as well as other earlier stage competitors.

In bipolar depression, we believe LB-102, if approved, would compete with several currently approved therapeutics, including: Vraylar (marketed by AbbVie Inc.); Caplyta (marketed by Janssen Pharmaceuticals, Inc.); quetiapine/quetiapineXR (marketed by AstraZeneca plc); Latuda (marketed by Sumitomo Pharma America, Inc.); and seroquel. We are also aware of several companies developing compounds for the treatment of bipolar depression, including Alto Neuroscience Inc., Neurocrine Biosciences, Inc., NRx Pharmaceuticals, Inc., and Xenon Pharmaceuticals Inc., as well as other earlier stage competitors.

In the adjunctive treatment of MDD, we believe LB-102, if approved, would compete with several currently approved therapeutics, including: Vraylar (marketed by AbbVie Inc.); Caplyta (marketed by Janssen Pharmaceuticals, Inc.); Rexulti (marketed by Otsuka Pharmaceutical Co. Ltd and H. Lundbeck A/S); aripiprazole (marketed by Otsuka Pharmaceutical Co. Ltd.); and quetiapine/quetiapineXR (marketed by AstraZeneca plc). We are also aware of several companies developing compounds for the adjunctive treatment of MDD, including Neurocrine Biosciences, Axsome Therapeutics, Inc., Neumora, Helus Pharma, as well as other earlier stage competitors.

Government Regulation

Government authorities in the United States, at the federal, state and, local level, and other countries extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, marketing, and export and import of human drug products. We, along with any third-party contractors, will be required to navigate the various preclinical, clinical and commercial approval requirements of the governing regulatory authorities of the countries in which we wish to conduct studies or seek approval of our product candidates. The process of obtaining regulatory approvals and ensuring compliance with applicable federal, state, local, and foreign statutes, regulations and requirements both during development and post-approval requires the expenditure of substantial time and financial resources.

U.S. Drug Development Process

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act of 1938, or the 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. Failure to comply with the applicable U.S. requirements at any time during the product development or approval process, or after approval, may subject an applicant to administrative or judicial sanctions brought by the FDA and the Department of Justice, or DOJ, or other governmental entities. The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests, animal studies and formulation studies in accordance with FDA's GLP regulations and other applicable requirements;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- approval by an IRB or ethics committee before each clinical trial may be initiated;

- performance of adequate and well-controlled human clinical trials in accordance with GCPs to evaluate the safety and efficacy of the proposed drug for its intended use;
- preparation of and submission to the FDA of an NDA;
- a determination by the FDA within 60 days of its receipt of an NDA to file the application for review;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of FDA inspections of the manufacturing facility or facilities at which the drug is produced to assess readiness for commercial manufacturing and conformance to the manufacturing-related elements of the application, to conduct a data integrity audit, and to assess compliance with current cGMP regulations to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity, and a potential inspection of selected clinical investigation sites to assess compliance with GCPs; and
- FDA review and approval of the NDA.

Preclinical Studies and IND Application

Once a product candidate is identified for development, it enters the preclinical development stage. The preclinical developmental stage generally involves laboratory evaluations of chemistry, formulation, and stability, as well as studies to evaluate the product candidate's toxicity, in an effort to support subsequent clinical testing. Such toxicity studies generally involve the use of animals, although an NDA applicant may fulfill nonclinical testing requirements by completing various *in vitro* assays (e.g., cell-based assays, organ chips, or microphysiological systems), *in silico* studies (i.e., computer modeling), other human or non-human biology-based tests (e.g., bioprinting), or *in vivo* animal tests.

Prior to beginning the first clinical trial with a product candidate in the United States, the product's developer, also referred to as the IND sponsor, must submit the results of preclinical testing, together with manufacturing information and analytical data, to the FDA as part of an IND. An IND is a request for authorization from the FDA to administer an investigational drug product to humans and must become effective before human clinical trials may begin. In addition to including the results of these nonclinical studies, the IND will also include a general investigational plan and a study protocol, detailing, among other things, the objectives of the clinical trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated, if the trial protocol includes an efficacy evaluation. The IND may also include any available human data or literature to support the use of the product candidate. Additional nonclinical testing may continue even after the IND is submitted.

The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, places the IND on clinical hold. In such case, the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial. Clinical holds also may be imposed by the FDA at any time after initiation of clinical trials due to safety concerns about ongoing or proposed clinical trials or non-compliance with specific FDA requirements, and the trials may not begin or continue until the FDA notifies the sponsor that the hold has been lifted. A clinical hold may affect one or more specific studies or all studies conducted under an active IND.

Human Clinical Trials in Support of an NDA

All clinical trials must be conducted under the supervision of one or more qualified investigators, generally physicians not employed by or under the trial sponsor's control, in accordance with GCPs, which include, among other things, the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial. Clinical trials must be conducted under protocols detailing, among other things, the objectives of the trial, dosing procedures, research subject selection and exclusion criteria, and the safety and effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND, and a separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent material amendments to a protocol. While the IND is active, progress reports summarizing the results of the clinical trials and nonclinical studies performed since the last progress report, among other information, must be submitted at least annually to the FDA. Sponsors also must submit written IND safety reports to the FDA and investigators in a timely matter for serious and unexpected suspected adverse events, findings from other studies suggesting a significant risk to humans exposed to the same or similar drugs, findings from animal or *in vitro* testing suggesting a significant risk to

humans, and any clinically important increased incidence of a serious suspected adverse reaction compared to that listed in the protocol or investigator brochure.

Furthermore, an IRB must review and approve the protocol before a clinical trial commences and must also approve the information regarding the trial and the consent form that must be signed by each research subject or the research subject's legal representative, monitor the study until completed, and otherwise comply with IRB regulations. Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives. In addition, some clinical trials also include oversight by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. Depending on its charter, this group may determine whether a trial may move forward at designated check points based on access to certain data from the trial. There are also requirements governing the reporting of ongoing clinical studies and clinical trial results to public registries, including clinicaltrials.gov.

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

- Phase 1: The product candidate is initially introduced into healthy human subjects or patients and tested for safety, dosage tolerance, absorption, metabolism, excretion, distribution and elimination, and, if possible, to gain an early indication of its effectiveness.
- Phase 2: The product candidate is administered to a limited patient population with a specified disease or condition to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product candidate for specific targeted diseases, and to determine dosage tolerance and optimal dosage.
- Phase 3: The product candidate is administered to an expanded patient population to further evaluate dosage, to provide substantial evidence of efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk-benefit ratio of the product candidate and provide an adequate basis for product labeling.

In some cases, the FDA may require, or sponsors may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product. These post-marketing clinical trials, sometimes referred to as Phase 4 studies, may be 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.

A pivotal trial is a clinical trial that adequately meets regulatory agency requirements for the evaluation of a product candidate's efficacy and safety such that it can be used to justify the approval of the product. Generally, pivotal trials are also Phase 3 trials but they may be Phase 2 trials if the trial design provides a reliable assessment of clinical benefit, particularly in situations where there is an unmet medical need.

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 alignment on the next phase of development.

Concurrent with clinical trials, companies usually complete additional nonclinical studies and must also develop additional information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product and, among other things, the manufacturer must develop methods for testing the identity, strength, quality, and purity of the finished drug product. In addition, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product does not undergo unacceptable deterioration over its shelf life.

Disclosure of Clinical Trial Information

Sponsors of clinical trials of certain FDA-regulated products, including prescription drugs, are required to register and disclose certain clinical trial information on a public registry maintained by the U.S. National Institutes of Health, or

NIH. In particular, information related to the product, patient population, phase of investigation, study sites and investigators and other aspects of the clinical trial is made public as part of the registration of the clinical trial. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs. Although sponsors are also obligated to disclose the results of their clinical trials after completion, disclosure of the results can be delayed in some cases for up to two years after the date of completion of the trial. Failure to timely register a covered clinical study or to submit study results as provided for in the law can give rise to civil monetary penalties and also prevent the non-compliant party from receiving future grant funds from the federal government.

U.S. Review and Approval Process

Assuming successful completion of the required clinical testing, the results of nonclinical studies and clinical trials, along with detailed descriptions of the manufacturing process, analytical tests conducted on the chemistry of the drug, proposed labeling and other relevant information are submitted to the FDA as part of an NDA requesting approval to market the product. The submission of an NDA is subject to the payment of a substantial user fee, unless a waiver or exemption applies. An annual program fee is also assessed on sponsors of approved prescription drug products. FDA adjusts these user and annual program fees on an annual basis.

The FDA conducts a preliminary review of all NDAs within the first 60 days after submission, before accepting them for filing, to determine whether they are sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the NDA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. Once filed, the FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use and whether it is being manufactured in accordance with cGMP requirements to assure and preserve the product's identity, strength, quality, and purity. Under the Prescription Drug User Fee Act, or PDUFA, policies that are currently in effect, the FDA has a goal of ten months from the filing date to complete its initial review of a standard application for a drug that is a new molecular entity, and six months from the filing date for an NDA that has been granted priority review. The FDA does not always meet its PDUFA goal dates, and the review process is often significantly extended by FDA requests for additional information or clarification and the sponsor's process to respond to such inquiries.

The FDA likely will re-analyze the clinical trial data, which could result in extensive discussions between the FDA and the applicant during the review process. The FDA also may require the development of a risk evaluation and mitigation strategy, or REMS, if it determines that a REMS is necessary to ensure that the benefits of the drug outweigh its risks and to assure the safe use of the product. The FDA determines the requirement for a REMS, as well as the specific REMS provisions, on a case-by-case basis. 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 can include medication guides, physician communication plans, and/or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools.

The FDA may refer an application for a novel drug to an advisory committee. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making product approval and risk mitigation decisions.

Before approving an NDA, the FDA will typically inspect the facility or facilities where 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 trial sites to assure that the clinical trials were conducted in compliance with GCP regulations and to assure the integrity of the clinical data submitted to the FDA. To ensure cGMP and GCP compliance by its employees and third-party contractors, an applicant must incur significant expenditure of time, money and effort in the areas of training, record keeping, production and quality control.

After the FDA completes its evaluation of the NDA and any inspections or advisory committee consultations, the agency will issue either an approval letter or a Complete Response Letter, or CRL, to the NDA applicant. An approval letter authorizes commercial marketing of the drug for specific indications for use. A CRL indicates that the review cycle of the application is complete, and the application will not be approved in its present form. A CRL usually describes the

specific deficiencies in the NDA identified by the FDA. Such deficiencies may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials or other significant and time-consuming requirements related to nonclinical studies or manufacturing. If a CRL is issued, the applicant may either resubmit the NDA, addressing all of the deficiencies that the FDA has identified in the letter, or withdraw the application. If and when those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the agency will issue an approval letter to the applicant. The FDA has committed to reviewing such resubmissions in response to an issued CRL in either two or six months depending on the type of information included. Even if such additional data and information are submitted, however, the FDA may ultimately decide that the NDA does not satisfy the regulatory criteria for approval.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. In addition, the FDA may require a sponsor to conduct Phase 4 testing, which involves clinical trials designed to further assess a drug's safety and effectiveness after NDA approval, and may require testing and surveillance programs to monitor the safety of approved products which have been commercialized. The FDA may also place other conditions on approval including the requirement for a risk evaluation and mitigation strategy, or REMS, to assure the safe use of the drug. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products.

In addition, the Pediatric Research Equity Act, or PREA, requires a sponsor to conduct pediatric clinical trials for most drugs; specifically, in relation to applications for a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration. Under PREA, original NDAs and supplements thereto must contain a pediatric assessment unless the sponsor has received a deferral or waiver. Sponsors must also submit Pediatric Study Plans, or PSPs, to the agency for review within sixty days of an end-of-Phase 2 meeting or, if there is no such meeting, as early as practicable before the initiation of the Phase 3 or Phase 2/3 clinical trial. The initial PSP must include an outline of the pediatric trial or trials that the sponsor plans to conduct, including trial objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric trials along with supporting information. The FDA and the sponsor must reach an agreement on the PSP. A sponsor can submit amendments to an agreed upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from nonclinical studies, early phase clinical trials or other clinical development programs.

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, unless a waiver or deferral has been granted. The FDA may defer, on its own initiative or upon the sponsor's request, submission of the pediatric assessments for some or all pediatric subpopulations until a specified date after approval. A deferral may be granted for several reasons, including a finding that the drug is ready for approval for use in adults before pediatric clinical trials are complete or that additional safety or effectiveness data needs to be collected before the pediatric clinical trials begin. The FDA must send a PREA non-compliance letter to any sponsor that fails to submit the required assessment, fails to keep a deferral current or fails to submit a request for approval of a pediatric formulation. The agency publicly posts such PREA non-compliance letters and sponsor's response.

Fast Track, Breakthrough Therapy, Priority Review Designations

The FDA offers a number of programs intended to expedite the development or review of a marketing application for an investigational drug. For example, the Fast Track designation program is intended to expedite or facilitate the process for developing and reviewing product candidates that 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 candidate and the specific indication for which it is being studied. The sponsor of a Fast Track product candidate has opportunities for more frequent interactions with the applicable FDA review team during development and, once an NDA is submitted, the application may be eligible for priority review. An NDA for a Fast Track product candidate may also be eligible for rolling review, where 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.

A product candidate intended to treat a serious or life-threatening disease or condition may also be eligible for Breakthrough Therapy designation to expedite its development and review. A product candidate can receive Breakthrough Therapy designation if preliminary clinical evidence indicates that the product candidate, alone or in combination with one or more other drugs, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includes all of the Fast Track program features, as well as more intensive FDA interaction and guidance beginning as early as Phase 1 and an organizational commitment to expedite the development and review of the product candidate, including involvement of senior managers.

In addition, an NDA may be eligible for priority review if the product candidate is designed to treat a serious condition, and if approved, would provide a significant improvement in safety or efficacy compared to available therapies for such disease or condition. The FDA will attempt to direct additional resources to the evaluation of a NDA designated for priority review in an effort to facilitate the review. For new-molecular-entity NDAs, priority review designation means the FDA's goal is to take action on the marketing application within six months of the 60-day filing date, as compared to ten months for review of new-molecular-entity NDAs under its current PDUFA review goals.

Fast Track designation, Breakthrough Therapy designation, and priority review do not change the standards for approval, but they may expedite the development or approval process. Even if a product candidate 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.

Post-Approval Requirements

Following approval of a new drug, the manufacturer and the approved product are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to monitoring and record-keeping, reporting of adverse experiences with the product, periodic reporting, product sampling and distribution, and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications, certain manufacturing changes and additional labeling claims, are subject to further FDA review and approval. Certain modifications may require the NDA sponsor to develop additional data or conduct additional nonclinical studies and clinical trials.

There also are continuing, annual program fees for any marketed products. 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 to assess compliance with cGMP requirements and other laws. The cGMP regulations include requirements relating to organization of personnel, buildings and facilities, equipment, control of components and drug product containers and closures, production and process controls, packaging and labeling controls, holding and distribution, laboratory controls, records and reports and returned or salvaged products. 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. FDA regulations also require investigation and correction of any deviations from cGMP requirements and impose reporting requirements on the NDA applicant and any third-party manufacturers involved in producing the approved drug product. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMPs and other aspects of quality control and quality assurance. 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 adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of requirements for post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS. 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;
- mandated modification of promotional materials or 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;

- fines, warning letters, or untitled letters;
- clinical holds on ongoing or planned 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; or
- injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising and promotion of prescription drug products following approval. A company can make only those claims relating to safety and efficacy 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, e.g., unapproved uses or unapproved patient populations. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Although 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 by us and approved by the FDA, manufacturers may not market or promote such uses. 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. Manufacturers may also share truthful and not misleading information about their products that is otherwise consistent with a product's FDA-approved labeling, which helps to support well-informed clinical decision-making by physicians and other health care professionals.

In addition, national distribution of pharmaceutical products is subject to the Drug Supply Chain Security Act.

Marketing and Data Exclusivity

Orange Book Listing

In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent with claims covering the applicant's product or method of using the product. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential generic competitors in support of approval of an ANDA. An ANDA provides for marketing of a drug product that has the same active ingredients in the same strengths and dosage form as the listed drug and has been shown to be bioequivalent to the listed drug. Other than the requirement for bioequivalence testing, ANDA applicants are not required to conduct, or submit results of, nonclinical or clinical tests to prove the safety or effectiveness of their drug product. Drugs approved in this way are commonly referred to as generic equivalents to the listed drug and can often be substituted by pharmacists under prescriptions written for the original listed drug.

The ANDA applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA's Orange Book. Specifically, the applicant must certify that: (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new product. The ANDA applicant may also elect to submit a Section VIII statement certifying that its proposed ANDA labeling does not contain (or carves out) any language regarding the patented method-of-use rather than certify to a listed method-of-use patent. If the applicant does not challenge the listed patents, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired.

A certification that the new product will not infringe the already approved product's listed patents, or that such patents are invalid, is called a Paragraph IV certification. If the ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been received by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA until the earlier of 30

months, expiration of the patent, settlement of the lawsuit, or a decision in the infringement case that is favorable to the ANDA applicant.

An applicant submitting an NDA under Section 505(b)(2) of the FD&C Act, also called a 505(b)(2) NDA, which permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by, or for, the applicant and for which the applicant has not obtained a right of reference, is required to certify to the FDA regarding any patents listed in the Orange Book for the approved product it references to the same extent that an ANDA applicant would.

Exclusivity

Regulatory exclusivity provisions under the FDCA can delay the submission or the approval of certain marketing applications that seek to reference an FDA-approved product. The FDCA provides a five-year period of non-patent data 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 accept for review an ANDA, or file a 505(b)(2) NDA, for another version of such drug where the applicant does not own or have a legal right of reference to such data required for approval. However, an application may be submitted after four years if it contains a Paragraph IV certification.

The FDCA alternatively provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA, or supplement to an existing NDA, if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the modification for which the drug received approval on the basis of the new clinical investigations and does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs referencing the approved application 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 that does not reference the approved application. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Pediatric exclusivity is another type of marketing exclusivity available in the United States. If granted, pediatric exclusivity provides for the attachment of an additional six months of marketing exclusivity to the term of any existing regulatory exclusivity or listed patents. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve another application. A product candidate may be eligible for this six-month period of exclusivity if the NDA sponsor conducts clinical trials in children and submits information requested in writing by the FDA, referred to as a Written Request, relating to the use of the product's active moiety in children. The issuance of a Written Request does not require the sponsor to undertake the described clinical trials. In addition, the clinical trial data do not need to show the product to be effective in the pediatric population studied; rather, the additional protection is granted if the pediatric clinical trial is deemed to have fairly responded to the FDA's Written Request. Although the FDA may issue a Written Request for studies on either approved or unapproved indications, it may only do so where it determines that information relating to that use of a product candidate in a pediatric population, or part of the pediatric population, may produce health benefits in that population.

Other U.S. Healthcare Laws and Compliance Requirements

In the United States, our current and future operations are subject to regulation by various federal, state and local authorities in addition to the FDA, including but not limited to, the Centers for Medicare & Medicaid Services, or CMS, other divisions of the U.S. Department of Health and Human Services, or HHS, (*e.g.*, the Office of Inspector General, the Office for Civil Rights), the U.S. DOJ and individual U.S. Attorney offices within the DOJ, the Federal Trade Commission, or FTC, and state and local governments. For example, our business practices, including our clinical research program and any future sales, marketing and scientific/educational grant programs may be required to comply with the anti-fraud and abuse laws the false claims laws, transparency requirements, and similar state laws, each as amended, as applicable.

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, in whole or in part, under Medicare, Medicaid or other federal healthcare programs. The term remuneration has been interpreted broadly to include anything of value. In addition, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation. Rather, if "one purpose" of the remuneration is to induce referrals, the federal Anti-Kickback Statute is violated. The federal Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on 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 future practices may not in all cases meet all of the criteria for protection under a statutory exception or regulatory safe harbor.

The civil monetary penalties statute imposes penalties against any person or entity who, among other things, is determined to have presented or caused to be presented a claim to, among others, a federal healthcare program that the person knows or should know is for a medical or other item or service that was not provided as claimed or is false or fraudulent.

The federal false claims laws, including the FCA, impose significant penalties and can be enforced by private citizens through civil qui tam actions, prohibit, any person or entity from, among other things, knowingly presenting, or causing to be presented, a false or fraudulent claim for payment to, or approval by, the federal government, including federal healthcare programs such as Medicare and Medicaid, 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. A claim includes "any request or demand" for money or property presented to the U.S. government. For instance, historically, pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies' marketing of the product for unapproved, off-label, and thus generally non-reimbursable, uses. In addition, a claim that includes items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created additional 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, willfully obstructing a criminal investigation of a healthcare offense, 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. Like 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 to have committed a violation.

In addition, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, imposes certain requirements on covered entities, which include certain healthcare providers, health plans and healthcare clearinghouses, and their business associates and covered subcontractors that receive or obtain protected health information in connection with providing a service on behalf of a covered entity relating to the privacy, security and transmission of individually identifiable health information.

Additionally, the federal Physician Payments Sunshine Act, or the 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) report information annually to CMS related to certain payments or other transfers of value made or distributed to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician practitioners (such as physician assistants and nurse practitioners), and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Failure to report accurately could result in penalties. In addition, many states also govern the reporting of payments or other transfers of value, many which differ from each other in significant

ways, are often not pre-empted, and may have a more prohibitive effect than the Sunshine Act, thus further complicating compliance efforts.

Also, many states have similar, and typically more prohibitive, 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. To distribute pharmaceutical products commercially in the future, should FDA approval be granted to any of our product candidates, we must comply with state laws that require the registration of manufacturers and wholesale distributors of drug 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. Several states have enacted legislation requiring pharmaceutical and biotechnology companies to establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, 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 and biotechnology companies for use in sales and marketing, and to prohibit certain other sales and marketing practices.

Ensuring business arrangements with third parties comply with applicable healthcare laws and regulations is a costly endeavor. If our operations are found to be in violation of any of the federal and state healthcare laws described above or any other current or future 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, individual 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, 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, 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.

Coverage, Pricing, and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we may 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 products. In the United States, third-party payors include federal and state healthcare programs, private managed care providers, health insurers and other organizations.

The process for determining whether a third-party payor will provide coverage for a product may be separate from the process for setting the price of a product or for establishing the reimbursement rate that such a payor will pay for the product. Third-party payors may limit coverage to specific products on an approved list, or also known as a formulary, which might not include all of the FDA-approved products for a particular indication. Third-party payors are increasingly challenging the price, examining the medical necessity and reviewing the cost-effectiveness of medical products, therapies and services, in addition to questioning their safety and efficacy. We may need to conduct expensive pharmaco-economic studies to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain the FDA approvals. Our product candidates may not be considered medically necessary or cost-effective. A payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. In addition, one payor's determination to provide coverage for a product does not ensure that other payors will also provide coverage for the product. Further, obtaining reimbursement for our product may be particularly difficult because of the higher prices often associated with branded drugs and drugs administered under the supervision of physicians. 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.

Under currently applicable U.S. law, certain products not usually self-administered (including injectable drugs) may be eligible for coverage under Medicare through Medicare Part B. Medicare Part B is part of original Medicare, the federal health care program that provides health care benefits to the aged and disabled, and covers outpatient services and supplies, including certain biopharmaceutical products, that are medically necessary to treat a beneficiary's health condition. As a condition of receiving Medicare Part B reimbursement for a manufacturer's eligible drugs, the manufacturer is required to participate in other government healthcare programs, including the Medicaid Drug Rebate Program and the 340B Drug Pricing Program. The Medicaid Drug Rebate Program requires pharmaceutical

manufacturers to enter into and have in effect a national rebate agreement with HHS as a condition for states to receive federal matching funds for the manufacturer's outpatient drugs furnished to Medicaid patients. Under the 340B Drug Pricing Program, the manufacturer must extend discounts to entities that participate in the program.

Additionally, the containment of healthcare costs has become a priority of federal, state and foreign governments. For example, HHS imposes rebates on many Medicare Part B and Medicare Part D products to penalize price increases that outpace inflation on an annual basis. HHS has also been empowered to negotiate the price of certain single-source drugs that have been on the market for at least seven (7) years covered under Medicare as part of the Medicare Drug Price Negotiation Program. Each year up to twenty (20) products will be selected by HHS for the Medicare Drug Price Negotiation Program. Products subject to the Medicare Drug Price Negotiation Program are expected to experience a significant reduction in reimbursement from the Medicare program on a per unit basis.

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 product candidate to currently available therapies. Other EU member states allow companies to fix their own prices for medicines, but monitor and control company profits. In addition, in some countries, cross-border imports from low-priced markets exert commercial pressure on pricing within a country.

The marketability of any product candidates for which we receive regulatory approval for commercial sale in any country or region may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. The downward pressure on the rise in healthcare costs in general and pharmaceutical products in particular has become intense. As a result, in the European Union, increasingly high barriers are being erected to the entry of new products. In the United States, the emphasis on managed care, the increasing influence of health maintenance organizations, and additional legislative changes has increased and we expect will continue to increase the pressure on product pricing. In addition, 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 receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Healthcare Reform in the U.S. and Potential Changes to Healthcare Laws

In the United States, there have been, and continue to be, legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities, and affect the profitable sale of product candidates that obtain marketing approval. The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay marketing approval of our product candidate. Moreover, among policy makers and payors in the United States, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. The pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product for which we obtain marketing approval.

The Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, or, collectively, the ACA, includes measures that have significantly changed the way healthcare is financed by both governmental and private insurers. There have been judicial, executive and congressional challenges and amendments to certain aspects of the ACA.

For example, on July 4, 2025, the One Big Beautiful Bill Act, or the OBBBA, was signed into law, which narrowed access to ACA marketplace exchange enrollment and declined to extend the ACA enhanced advanced premium tax credits that expired at the end of 2025, which, among other provisions in the law, are anticipated to reduce the number of Americans with health insurance. The OBBBA also is expected to reduce Medicaid spending and enrollment by implementing work requirements for some beneficiaries, capping state-directed payments, reducing federal funding, and limiting provider taxes used to fund the program. Congress is considering proposed legislation intended to further reduce

healthcare costs with alternatives to replace the expired ACA subsidies. We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures. Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of 2% per fiscal year, which began in 2013 and will remain in effect until 2032 unless additional Congressional action is taken. The current administration is pursuing policies to reduce regulations and expenditures across government agencies including at HHS, the FDA, CMS and related agencies. These actions, presently directed by executive orders or memoranda from the Office of Management and Budget, may propose policy changes that create additional uncertainty for our business. For example, the current administration has announced agreements with several pharmaceutical companies that require the drug manufacturers to offer, through a direct-to-consumer platform (TrumpRx), U.S. patients and Medicaid programs prescription drug Most-Favored Nation pricing equal to or lower than those paid in other developed nations, with additional mandates for direct-to-patient discounts and repatriation of foreign revenues. Other recent actions, for example, include (1) directing agencies to reduce agency workforce and cut programs; (2) directing HHS and other agencies to lower prescription drug costs through a variety of initiatives; (3) imposing tariffs on imported pharmaceutical products; and (4) as part of the Make America Healthy Again Commission's Strategy Report released in September 2025, working across government agencies to increase enforcement on direct-to-consumer pharmaceutical advertising. Additionally, the current administration recently called on Congress to enact "The Great Healthcare Plan," to codify and expand Most-Favored Nation pricing, lower government subsidies to private insurance companies, increase healthcare price transparency, expand pharmaceutical drugs available for over-the-counter purchase, and enact restrictions on pharmacy benefit manager payment methodologies, among other things. These actions and policies may significantly reduce U.S. drug prices, potentially impacting manufacturers' global pricing strategies and profitability, while increasing their operational costs and compliance risks. In June 2024, the U.S. Supreme Court's Loper Bright decision greatly reduced judicial deference to regulatory agencies, which could increase successful legal challenges to federal regulations affecting our operations. Congress may introduce and ultimately pass health care related legislation that could impact the drug approval process and make changes to the Medicare Drug Price Negotiation Program.

Individual states in the United States have also become increasingly active in passing legislation and implementing 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 expect that the healthcare reform measures that have been adopted and 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 product and could seriously harm our future revenues. 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 products, if approved.

Foreign Government Regulation

To market any product outside of the United States, we would need to comply with numerous and varying regulatory requirements of other countries governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of our products.

Whether or not we obtain FDA approval of a product candidate, 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. Approval by one regulatory authority does not ensure approval by regulatory authorities in other jurisdictions. The approval process varies from country to country, can involve additional testing beyond that required by FDA, and may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing, promotion, and reimbursement vary greatly from country to country. Failure to comply with applicable foreign regulatory requirements, may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Clinical Trials in the EU

Similarly to the United States, the various phases of non-clinical and clinical research in the European Union, or EU are subject to significant regulatory controls.

Non-clinical studies are performed to demonstrate the health or environmental safety of new chemical or biological substances. Non-clinical studies must be conducted in compliance with the principles of good laboratory practice, GLP, as set forth in Directive 2004/10/EC. These GLP standards reflect the Organization for Economic Co-operation and Development requirements.

Clinical trials of medicinal products in the EU must be conducted in accordance with the Clinical Trials Regulation (EU) No 536/2014, and national regulations and the International Conference on Harmonization, guidelines on GCPs, as well as the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

EU Review and Approval process

In the EU, medicinal products can only be commercialized after a related marketing authorization, or MA, has been granted. To obtain an MA for a product in the EU, an applicant must submit a Marketing Authorization Application, or MAA, either under a centralized procedure administered by the European Medicines Agency, or EMA, or one of the procedures administered by the competent authorities of EU Member States (decentralized procedure, national procedure or mutual recognition procedure). An MA may be granted only to an applicant established in the EU.

The centralized procedure provides for the grant of a single MA by the European Commission that is valid throughout the EEA (which is comprised of the 27 EU Member States plus Norway, Iceland and Liechtenstein). Pursuant to Regulation (EC) No 726/2004, the centralized procedure is compulsory for specific products, including for (i) medicinal products derived from biotechnological processes, (ii) products designated as orphan medicinal products, (iii) advanced therapy medicinal products, or ATMPs, and (iv) products with a new active substance indicated for the treatment of HIV/AIDS, cancer, neurodegenerative diseases, diabetes, auto-immune and other immune dysfunctions and viral diseases. For products with a new active substance indicated for the treatment of other diseases and products that are highly innovative or for which a centralized process is in the interest of patients, authorization through the centralized procedure is optional on related approval. Under the centralized procedure, the EMA's Committee for Medicinal Products for Human Use, or CHMP, conducts the initial assessment of a product. The CHMP is also responsible for several post-authorization and maintenance activities, such as the assessment of modifications or extensions to an existing MA. The maximum timeframe for the evaluation of an MAA under the centralized procedure is 210 days, excluding clock stops when additional information or written or oral explanation is to be provided by the applicant in response to questions of the CHMP.

The decentralized MA procedure requires a separate application to, and leads to separate approval by, the competent authorities of each EU Member State in which the product is to be marketed. This application is identical to the application that would be submitted to the EMA for authorization through the centralized procedure. The reference EU Member State prepares a draft assessment and drafts of the related materials within 120 days after receipt of a valid application. The resulting assessment report is submitted to the concerned EU Member States who, within 90 days of receipt, must decide whether to approve the assessment report and related materials. If a concerned EU Member State cannot approve the assessment report and related materials due to concerns relating to a potential serious risk to public health, disputed elements may be referred to the Heads of Medicines Agencies' Coordination Group for Mutual Recognition and Decentralised Procedures—Human, or CMDh, for review. The subsequent decision of the European Commission is binding on all EU Member States.

The mutual recognition procedure allows companies that have a medicinal product already authorized in one EU Member State to apply for this authorization to be recognized by the competent authorities in other EU Member States. Like the decentralized procedure, the mutual recognition procedure is based on the acceptance by the competent authorities of the EU Member States of the MA of a medicinal product by the competent authorities of other EU Member States. The holder of a national MA may submit an application to the competent authority of an EU Member State requesting that this authority recognize the MA delivered by the competent authority of another EU Member State.

An MA has, in principle, an initial validity of five years. The MA may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance by the EMA or by the competent authority of the EU Member State in which the original MA was granted. To support the application, the MA holder must provide the EMA or the competent authority with a consolidated version of the Common Technical Document providing up-to-date data concerning the quality, safety and efficacy of the product, including all variations introduced since the MA was granted, at least nine months before the MA ceases to be valid. The European Commission or the competent authorities of the EU Member States may decide on justified grounds relating to pharmacovigilance, to proceed with one further five year renewal period for the MA. Once

subsequently definitively renewed, the MA shall be valid for an unlimited period. Any authorization which is not followed by the actual placing of the medicinal product on the EU market (for a centralized MA) or on the market of the authorizing EU Member State within three years after authorization ceases to be valid (the so-called sunset clause).

Accelerated and Abbreviated Pathways in the EU

Innovative products that target an unmet medical need and are expected to be of major public health interest may be eligible for a number of expedited development and review programs, such as the Priority Medicines, or PRIME, scheme, which provides incentives similar to the breakthrough therapy designation in the U.S. PRIME is a voluntary scheme aimed at enhancing the EMA's support for the development of medicinal products that target unmet medical needs. Eligible products must target conditions for which there is an unmet medical need (there is no satisfactory method of diagnosis, prevention or treatment in the EU or, if there is, the new medicinal product will bring a major therapeutic advantage) and they must demonstrate the potential to address the unmet medical need by introducing new methods of therapy or improving existing ones. Benefits accrue to sponsors of product candidates with PRIME designation, including but not limited to, early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and potentially accelerated MAA assessment once a dossier has been submitted. Accelerated assessment may be granted by the CHMP in exceptional cases, when a medicinal product targeting an unmet medical need is expected to be of major interest from the point of view of public health and, in particular, from the viewpoint of therapeutic innovation. If the CHMP accepts a request for accelerated assessment, the time limit of 210 days will be reduced to 150 days (excluding clock stops). The CHMP can, however, revert to the standard time limit for the centralized procedure if it considers that it is no longer appropriate to conduct an accelerated assessment.

In the EU, a "conditional" MA may be granted in cases where all the required safety and efficacy data are not yet available. The European Commission may grant a conditional MA for a medicinal product if it is demonstrated that all of the following criteria are met: (i) the benefit-risk balance of the medicinal product is positive; (ii) it is likely that the applicant will be able to provide comprehensive data post-authorization; (iii) the medicinal product fulfils an unmet medical need; and (iv) the benefit of the immediate availability to patients of the medicinal product is greater than the risk inherent in the fact that additional data are still required. The conditional MA is subject to conditions to be fulfilled for generating the missing data or ensuring increased safety measures. It is valid for one year and must be renewed annually until all related conditions have been fulfilled. Once any pending studies are provided, the conditional MA can be converted into a traditional MA. However, if the conditions are not fulfilled within the timeframe set by the EMA and approved by the European Commission, the MA will cease to be renewed.

An MA may also be granted "under exceptional circumstances" where the applicant can show that it is unable to provide comprehensive data on efficacy and safety under normal conditions of use even after the product has been authorized and subject to specific procedures being introduced. These circumstances may arise in particular when the intended indications are very rare and, in the state of scientific knowledge at that time, it is not possible to provide comprehensive information, or when generating data may be contrary to generally accepted ethical principles. Like a conditional MA, an MA granted in exceptional circumstances is reserved to medicinal products intended to be authorized for treatment of rare diseases or unmet medical needs for which the applicant does not hold a complete data set that is required for the grant of a standard MA. However, unlike the conditional MA, an applicant for authorization in exceptional circumstances is not subsequently required to provide the missing data. Although the MA "under exceptional circumstances" is granted definitively, the risk-benefit balance of the medicinal product is reviewed annually, and the MA will be withdrawn if the risk-benefit ratio is no longer favorable.

Pediatric Development

In the EU, Regulation (EC) No 1901/2006 provides that all MAAs for new medicinal products have to include the results of trials conducted in the pediatric population, in compliance with a pediatric investigation plan, or PIP, agreed with the EMA's Pediatric Committee, or PDCO. The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the medicinal product for which MA is being sought. The PDCO can grant a deferral of the obligation to implement some or all of the measures provided in the PIP until there are sufficient data to demonstrate the efficacy and safety of the product in adults. Further, the obligation to provide pediatric clinical trial data can be waived by the PDCO when these data are not needed or appropriate because the product is likely to be ineffective or unsafe in children, the disease or condition for which the product is intended occurs only in adult populations, or when the product does not represent a significant therapeutic benefit over existing treatments for pediatric patients. Once the MA is

obtained in all EU Member States and study results are included in the product information, even when negative, the product is eligible for a six-month extension to the Supplementary Protection Certificate, or SPC, if any is in effect at the time of authorization or, in the case of orphan medicinal products, a two-year extension of orphan market exclusivity.

Data and Market Exclusivity in the EU

The EU provides opportunities for data and market exclusivity related to MAs. Upon receiving an MA, innovative medicinal products are generally entitled to receive eight years of data exclusivity and 10 years of market exclusivity. Data exclusivity, if granted, prevents regulatory authorities in the EU from referencing the innovator's data to assess a generic application or biosimilar application for eight years from the date of authorization of the innovative product, after which a generic or biosimilar MAA can be submitted, and the innovator's data may be referenced. The market exclusivity period prevents a successful generic or biosimilar applicant from commercializing its product in the EU until 10 years have elapsed from the initial MA of the reference product in the EU. The overall ten-year period may, occasionally, be extended for a further year to a maximum of 11 years if, during the first eight years of those ten years, the MA holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. However, there is no guarantee that a product will be considered by the EU's regulatory authorities to be a new chemical/biological entity, and products may not qualify for data exclusivity.

In April 2023, the European Commission issued a proposal to revise and replace the existing general pharmaceutical legislation, which was supported in large part by the European Parliament in April 2024. Additional procedural steps remain in the European legislative process and the proposed legislation is not expected to be adopted until at least 2026. If adopted and implemented as currently proposed, these legislative revisions will significantly change several aspects of drug development and approval in the EU.

Post-authorization Requirements in the EU

Where an MA is granted in relation to a medicinal product in the EU, the holder of the MA is required to comply with a range of regulatory requirements applicable to the manufacturing, marketing, promotion and sale of medicinal products. Similar to the United States, both MA holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA, the European Commission and/or the competent regulatory authorities of the individual EU Member States. The holder of an MA must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance who is responsible for oversight of that system. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports, or PSURs.

All new MAAs must include a risk management plan, or RMP, describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the MA. Such risk- minimization measures or post-authorization obligations may include additional safety monitoring, more frequent submission of PSURs, or the conduct of additional clinical trials or post-authorization safety studies.

In the EU, the advertising and promotion of medicinal products are subject to both EU and EU Member States' laws governing promotion of medicinal products, interactions with physicians and other healthcare professionals, misleading and comparative advertising and unfair commercial practices. General requirements for advertising and promotion of medicinal products, such as direct-to-consumer advertising of prescription medicinal products are established in EU law. However, the details are governed by regulations in individual EU Member States and can differ from one country to another. Interactions between pharmaceutical companies and health care professionals are also governed by strict laws, such as national anti-bribery laws of European countries, national sunshine rules, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct.

Pricing, Coverage and Reimbursement in the EU

In the EU, pricing and reimbursement schemes vary widely from country to country. For example, some countries provide that products may be marketed only after an agreement on reimbursement price has been reached. Such pricing negotiations with governmental authorities can take considerable time after receipt of marketing approval for a product. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations

may continue after reimbursement has been obtained. In addition, the EU provides options for its Member States to restrict the range of products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. EU Member States may approve a specific price for a product, may adopt a system of direct or indirect controls on the profitability of the company placing the product on the market. Other EU Member States allow companies to fix their own prices for products but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. In addition, some EU Member States may require the completion of additional studies that compare the cost-effectiveness of a particular medicinal product candidate to currently available therapies. This Health Technology Assessment, or HTA, process is the procedure according to which the assessment of the public health impact, therapeutic impact and the economic and societal impact of use of a given medicinal product in the national healthcare systems of the individual country is conducted. The outcome of HTA regarding specific medicinal products will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU Member States.

The Foreign Corrupt Practices Act

The 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 to assist the individual or business in obtaining or retaining business. United States authorities that enforce the FCPA, including the DOJ, deem most health care professionals and other employees of foreign hospitals, clinics, research facilities and medical schools in countries with public health care or public education systems to be "foreign officials" under the FCPA. 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.

Additional Regulation

In addition to the foregoing, state, federal, and foreign laws regarding environmental protection and hazardous substances, including the Occupational Safety and Health Act, the Resource Conservancy and Recovery Act and the Toxic Substances Control Act, affect our business. These and other laws govern our use, handling and disposal of various biological, chemical and radioactive substances used in, and wastes generated by, our operations. If our operations result in contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and governmental fines. We believe that we are in material compliance with applicable environmental laws and that continued compliance therewith will not have a material adverse effect on our business. We cannot predict, however, how changes in these laws may affect our future operations.

Data Privacy and Security

Numerous state, federal, and foreign laws, regulations, standards, and other obligations govern the collection, use, access to, confidentiality, security, and other processing of personal information, including clinical trial data, and apply, or could apply in the future, to our operations or the operations of our partners. In the United States, numerous federal and state laws and regulations, including data breach notification laws, health information privacy and security laws, and consumer protection laws and regulations, govern the collection, use, disclosure, protection, and other processing of personal information. Further, as we collect personal data from individuals outside of the United States, through clinical trials or otherwise, we are and could become subject to foreign laws, such as the GDPR, which govern the privacy and security of personal data, including health-related data. Our use of artificial intelligence (including machine learning) may also be subject to evolving laws and regulations, including those related to controlling for data bias and anti-discrimination. Privacy and security laws, regulations and other obligations are constantly evolving, may conflict with each other to complicate compliance efforts, and can result in investigations, proceedings, or actions that may lead to significant civil and/or criminal penalties and restrictions on data processing.

Employees and Human Capital Resources

As of December 31, 2025, we had 27 total full-time employees. Of our 27 employees, three hold Ph.D. and/or M.D. degrees and 15 were engaged in research and development. None of our employees are subject to a collective bargaining agreement. We consider our relationship with our employees to be good.

We recognize that our continued ability to attract, retain, and motivate exceptional employees is vital to ensuring our long-term competitive advantage. Our employees are critical to our long-term success and are essential to helping us

meet our goals. Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing, and integrating our existing and additional employees. The principal purposes of our equity incentive plans are to attract, retain, and motivate selected employees, consultants, and directors through the granting of stock-based compensation awards and cash-based performance bonus awards.

Properties and Facilities

Our principal office is located at One Pennsylvania Plaza, Suite 1025, New York, NY 10119, where we lease approximately 8,900 square feet of office space under a lease that will expire in 2032. In November 2025, we entered into an amendment of the lease for an additional 4,600 square feet of office space that will commence upon the delivery of the additional space in 2026 and will expire in 2032. We believe that our existing facility and the expansion are adequate to meet our current needs, and that suitable additional alternative spaces will be available in the future on commercially reasonable terms.

Corporate Information

We were incorporated under the laws of the State of Delaware in September 2015 under the name "LB Pharmaceuticals Inc." Our principal executive office is located at One Pennsylvania Plaza, Suite 1025, New York, NY 10119.

Our telephone number is (212) 605-0300. We completed our initial public offering in September 2025 and our common stock is listed on the Nasdaq Global Market under the symbol "LBRX."

Available Information

Our website address is lbpharma.us and our investor relations website address is https://ir.lbpharma.us. Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Sections 13(a) and 15(d) of the Exchange Act are available free of charge on our investor relations website as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. The SEC maintains an internet site that contains reports, proxy and information statements and other information. The address of the SEC's website is www.sec.gov.

Further corporate governance information, including our corporate governance guidelines and board committee charters, is also available on our investor relations website under the heading "Corporate Governance." The contents of our websites are not intended to be incorporated by reference into this Annual Report on Form 10-K or in any other report or document we file with the SEC, and any references to our websites are intended to be inactive textual references only.

RISK FACTORS SUMMARY

Our business is subject to numerous risks and uncertainties and are subject to change based on various factors, including those highlighted in the section entitled "Risk Factors" in Part I, Item 1A of this Annual Report on Form 10-K. These risks include, but are not limited to, the following:

- We are a clinical-stage biopharmaceutical company with a limited operating history and no history of commercializing products, which may make it difficult to evaluate our approach to the discovery and development of our product candidate and the prospects for our future viability.
- We have incurred substantial losses since our inception. We anticipate incurring substantial and increasing losses for the foreseeable future and may never achieve or maintain profitability.
- We will require substantial additional financing to achieve our goals, and failure to obtain additional capital when needed, or on acceptable terms to us, could cause us to delay, limit, reduce, or terminate our product development or future commercialization efforts.
- We have concentrated our research and development efforts on the treatment of psychiatric and neurological conditions, a field that faces certain challenges in drug development.
- The obligations from our royalty agreements may be a drain on our cash resources or may cause us to incur debt obligations to satisfy the payment obligations.
- Preclinical and clinical development involves a lengthy and expensive process, with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial or real-world results. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our current product candidate or any future product candidates.
- Even if we complete the necessary preclinical studies and clinical trials, the marketing approval process is expensive, time-consuming, and uncertain and may prevent us or any future collaboration partners from obtaining approvals for the commercialization of our product candidate.
- Even if our product candidate receives regulatory approval, it may fail to achieve the degree of market acceptance by physicians, patients, and others in the medical community necessary for commercial success, in which case we may not generate significant revenues or become profitable.
- The successful commercialization of our product candidate, if approved, will depend in part on the extent to which governmental authorities and health insurers establish coverage, adequate reimbursement levels, and favorable pricing policies. Failure to obtain or maintain coverage and adequate reimbursement for our product candidate could limit our ability to market those products and decrease our ability to generate revenue.
- Our business depends on the success of our product candidate. If we are ultimately unable to successfully commercialize our product candidate, or experience significant delays in doing so, our business will be materially harmed.
- We rely on, and intend to continue to rely on, our internal clinical development expertise to conduct our current and future clinical trials. This model includes internal teams and systems as well as external vendors and CROs to comprise a full clinical trial team. If our clinical trial team does not comply with applicable regulatory requirements, meet expected deadlines, or run trials effectively, our development programs and our ability to seek or obtain regulatory approval for or commercialize our product candidate may be delayed.
- Competitive products may reduce or eliminate the commercial opportunity for our product candidate for our current or future indications. If our competitors develop technologies or product candidates more rapidly than we do, or their technologies are more effective or safer than ours, our ability to develop and successfully commercialize our current products may be adversely affected.
- We are dependent on the services of our management and other clinical and scientific personnel, and if we are not able to retain these individuals or recruit additional management or clinical and scientific personnel, our business will suffer.

- If we are unable to obtain and maintain sufficient intellectual property protection for our technologies, and product candidate and any future product candidates we may develop, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors or other third parties could develop and commercialize products similar or identical to ours, and our ability to successfully develop and commercialize our product candidate may be adversely affected.
- Patent terms may be inadequate to protect our competitive position on our product candidate for a sufficient amount of time.
- We rely on third-party manufacturers and suppliers to supply our product candidate. The loss of our third-party manufacturers or suppliers, or their failure to comply with applicable regulatory requirements or to supply sufficient quantities at acceptable quality levels or prices, within acceptable timeframes, or at all, would materially and adversely affect our business.

The material and other risks summarized above should be read together with the text of the full risk factors and in the other information set forth in this Annual Report on Form 10-K, including our condensed financial statements and the related notes, as well as in other documents that we file with the SEC. If any such material and other risks and uncertainties actually occur, our business, prospects, financial condition and results of operations could be materially and adversely affected. The risks summarized above or described in full are not the only risks that we face. Additional risks and uncertainties not currently known to us, or that we currently deem to be immaterial may also materially adversely affect our business, prospects, financial condition and results of operations.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below, together with all of the other information contained in this Annual Report on Form 10-K, including our financial statements and their related notes included elsewhere herein and the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" before making an investment decision. If any of the following risks actually occurs, our business, prospects, operating results, and financial condition could suffer materially, the trading price of our common stock could decline, and you could lose all or part of your investment. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently believe to be immaterial also may materially and adversely affect our business, prospects, operating results, and financial condition.

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

We are a clinical-stage biopharmaceutical company with a limited operating history and no history of commercializing products, which may make it difficult to evaluate our approach to the discovery and development of our product candidate and the prospects for our future viability.

We are a clinical-stage biopharmaceutical company with a limited operating history. We were formed in 2015 and our operations to date have been limited to organizing, staffing, and financing our company, conducting research and development activities, conducting clinical trials for our product candidate, and establishing our intellectual property portfolio. If we are successful in achieving regulatory approval for our product candidate in the future, we will eventually need to transition from a company with a development focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

Our approach to the discovery and development of our product candidate is unproven, and we do not know whether we will be able to develop any product candidate that succeeds in clinical development or products of commercial value. Moreover, as an organization, we have not yet demonstrated an ability to obtain regulatory approvals, manufacture a commercial-scale product or arrange for a third party to do so on our behalf, conduct sales and marketing activities necessary for successful product commercialization, or generate revenues. We may encounter unforeseen expenses, difficulties, complications, delays, and other known or unknown factors in achieving our business objectives. Accordingly, you should consider our prospects in light of the costs, uncertainties, delays, and difficulties frequently encountered by companies in clinical development, especially clinical-stage biopharmaceutical companies such as ours. Any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing pharmaceutical products.

We have incurred substantial losses since our inception. We anticipate incurring substantial and increasing losses for the foreseeable future and may never achieve or maintain profitability.

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 efficacy 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 from product sales to date. As a result, we are not profitable, have incurred substantial losses in each period since our inception, and we expect to incur significant losses for the foreseeable future.

For the year ended December 31, 2025, our net loss was approximately $25.2 million. As of December 31, 2025, we had an accumulated deficit of approximately $129.5 million. Substantially all of our losses have resulted from expenses incurred in connection with the development of our pipeline, research and development, clinical trial costs, and from general and administrative costs associated with our operations. We expect to incur significant losses for the foreseeable future, and we expect these losses to increase as we continue our development of our product candidate. We anticipate that our expenses will increase substantially if, and as, we:

- conduct further clinical trials for LB-102 in patients with schizophrenia and bipolar depression, and initiate clinical development of LB-102 in adjunctive MDD, and other neuropsychiatric indications, and advance our preclinical programs into the clinic;

- identify additional product candidates and acquire rights from third parties to those product candidates through licenses or other acquisitions, and conduct development activities, including preclinical studies and clinical trials;
- procure the manufacturing of preclinical, clinical, and commercial supply of our current and future product candidates;
- seek regulatory approvals for our product candidate or any future product candidates;
- commercialize our current product candidate or any future product candidates, if approved;
- take steps toward our goal of being an integrated biopharmaceutical company capable of supporting commercial activities, including establishing sales, marketing and distribution infrastructure;
- attract, hire, and retain qualified clinical, scientific, operations, and management personnel;
- add and maintain operational, financial, and information management systems;
- protect, maintain, enforce, and defend our rights in our intellectual property portfolio;
- defend against third-party interference, infringement, and other intellectual property claims, if any;
- address any competing therapies and market developments;
- experience any delays in our preclinical studies or clinical trials and regulatory approval for our product candidate due to macroeconomic conditions, geopolitical conflicts, or other global events, including any health epidemics and their residual effects; and
- incur additional costs, including legal, accounting, and other expenses, associated with operating as a public company.

We have no product candidates approved for commercial sale and have not generated any revenue from the sale of products. Our ability to become and remain profitable depends on our ability to generate revenue. We do not expect to generate significant revenue, if any, unless and until we, either alone or with a collaborator, are able to obtain regulatory approval for, and successfully commercialize, our product candidate for its initial and potential additional indications, or any other product candidates we may develop in the future.

Successful commercialization will require achievement of many key milestones, including demonstrating each product candidate's safety and efficacy in clinical trials, obtaining regulatory approval for these product candidates, manufacturing, marketing, and selling those products for which we, or any of our future collaborators, may obtain regulatory approval, satisfying any post-marketing requirements, and obtaining reimbursement for our products from private insurance or government payors. Because of the uncertainties and risks associated with these activities, we are unable to accurately and precisely predict the timing and amount of revenues, the extent of any further losses, or if or when we might achieve profitability. We and any future collaborators may never succeed in these activities and, even if we do, or any future collaborators do, we may never generate revenues that are large enough for us 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. Additionally, our expenses could increase if we are required by the FDA or any comparable foreign regulatory authority to perform clinical trials in addition to those currently expected, or if there are any delays in completing our clinical trials or in the nonclinical or manufacturing-related activities associated with the development of our product candidate.

Even if we succeed in commercializing LB-102, we expect to incur substantial development costs and other expenditures to develop and market additional product candidates. We may also encounter unforeseen expenses, difficulties, complications, delays, and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue or raise additional capital. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and our working capital. Our failure to become and remain profitable may depress the market price of our common stock and could impair our ability to raise capital, expand our business, diversify our product offerings, or continue our operations. If we continue to suffer losses as we have in the past, you may not receive any return on your investment and may lose your entire investment.

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

Our operations have consumed substantial amounts of cash since our inception. We expect to continue to spend substantial amounts of cash to conduct further research and development, preclinical studies, and clinical trials of our current and any future product candidates, to seek regulatory approvals for our product candidate, and to launch and commercialize any products if we receive regulatory approval.

As of December 31, 2025, we had $295.2 million of cash, cash equivalents and marketable securities. Based upon our current operating plan, we believe that our existing cash, cash equivalents and marketable securities will enable us to fund our operating expenses and capital expenditure requirements for at least the next 12 months. Our future capital requirements and the period for which our existing resources will support our operations may vary significantly from what we expect, and we will, in any event, require additional capital in order to complete clinical development of our current program. Our monthly spending levels will vary based on new and ongoing development and corporate activities. Because the length of time and activities associated with development of our programs and product candidate are highly uncertain, we are unable to estimate the actual funds we will require for development and any approved marketing and future commercialization activities, if any. Our future capital requirements will depend on many factors, including:

- the scope, timing, progress, costs, and results of discovery, preclinical development, and clinical trials for our current or future product candidates;
- the number of clinical trials required for regulatory approval of our current or future product candidates, which may differ between the United States and other countries or regions;
- the costs, timing, and outcome of regulatory review of any of our current or future product candidates;
- the costs associated with acquiring or licensing additional product candidates, technologies, or assets, including the timing and amount of any milestones, royalties, or other payments due in connection with our acquisitions and licenses;
- the cost of manufacturing clinical and commercial supplies and any other activities related thereto of our current or future product candidates;
- the costs and timing of preparing, filing, and prosecuting patent applications, maintaining and enforcing our intellectual property rights, and defending any intellectual property-related claims, including any claims by third parties that we are infringing upon their intellectual property rights;
- our ability to maintain existing, and establish new, strategic collaborations or other arrangements and the financial terms of any such agreements, including the timing and amount of any future milestone, royalty, or other payments due under any such agreement;
- the costs and timing of future commercialization activities, including manufacturing, marketing, sales, and distribution, for any product candidate for which we receive marketing approval;
- the revenue, if any, received from commercial sales of the product candidate(s) for which we receive marketing approval;
- expenses to attract, hire, and retain skilled personnel for us to grow as an organization and achieve our business objectives;
- the costs of operating as a public company;
- our ability to establish a commercially viable pricing structure and obtain approval for coverage and adequate reimbursement from third-party and government payors for any products that receive marketing approval;
- our ability to mitigate the impact of adverse macroeconomic conditions or geopolitical events, including any health epidemics and their residual effects, the ongoing conflicts between Ukraine and Russia, bank failures, or inflation and increased interest rates, on our preclinical and clinical development or operations;
- the effect of competing technological and market developments; and
- the extent to which we acquire or invest in businesses, products, and technologies.

We will require substantial additional capital to achieve our business objectives. Additional funds may not be available on a timely basis, on favorable terms or at all, and such funds, if raised, may not be sufficient to enable us to continue to implement our long-term business strategy. Market volatility resulting from adverse macroeconomic conditions or geopolitical events, including the ongoing war between Ukraine and Russia and unrest in the Middle East, bank failures, inflation, increased interest rates, or other factors, may further adversely impact our ability to access capital as and when needed. Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through equity offerings, debt financings, or other capital sources, including potential collaborations, licenses, and other similar arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a holder of our common stock. Any future debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, selling or licensing our assets, making capital expenditures, declaring dividends, or encumbering our assets to secure future indebtedness. Such restrictions could adversely impact our ability to conduct our operations and execute our business plan.

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

We have concentrated our research and development efforts on the treatment of psychiatric and neurological conditions, a field that faces certain challenges in drug development.

We have focused our research and development efforts on the treatment of psychiatric and neurological conditions. Efforts by biotechnology and pharmaceutical companies in this field have faced certain challenges in drug development. In particular, clinical trials focused on many neuroscience diseases, such as schizophrenia, bipolar depression and adjunctive MDD, rely on subjective patient-reported outcomes as key endpoints. This makes these trials more difficult to evaluate than indications with more objective endpoints. Furthermore, these indications are often subject to a higher placebo effect, which may make it more challenging to isolate the beneficial effects of our product candidate. While a product candidate may show clinical activity or therapeutic benefit, a high placebo effect in a clinical trial will make it difficult to ascertain that benefit or to show a statistically significant effect of the product candidate as compared to the control arm, which may ultimately cause a clinical trial to fail or otherwise not translate to actual clinical benefit. Moreover, the risk for this higher placebo effect can increase from successful completion of a Phase 2 trial to a Phase 3 trial, as there is clinical evidence of therapeutic benefit to which patients would already be aware of. There can be no guarantee that we will successfully overcome these challenges in our ongoing or any future clinical trials of our product candidate or that we will not encounter other challenges in the development of our product candidate. In addition, negative investor perception of our clinical trial results due to a high placebo effect may adversely affect our stock price.

For example, certain of our primary or secondary endpoints in our clinical trials, including our completed Phase 2 trial of LB-102 in patients with acute schizophrenia, involve subjective assessments by physicians and/or patients, which can increase the uncertainty of clinical trial outcomes. The primary endpoint of our Phase 3 acute schizophrenia trial is to evaluate the efficacy of LB-102 compared to the placebo, as measured by change from baseline in PANSS total score at six weeks, which requires patients and raters to undertake a questionnaire regarding symptoms at protocol specified timepoints in the trial. This and other assessments are inherently subjective, which can increase the variability of clinical results across clinical trials and create a significant degree of uncertainty in determining overall clinical benefit. Accordingly, these subjective assessments can complicate clinical trial design, adversely impact the ability of a study to show a statistically significant improvement, and generally adversely impact a clinical development program by introducing additional uncertainties.

The obligations from our royalty agreements may be a drain on our cash resources or may cause us to incur debt obligations to satisfy the payment obligations.

In August 2023, contemporaneously with the closing of our Series C financing, we entered into several amended and restated royalty participation agreements, or the Amended and Restated Royalty Agreements, with certain of our existing investors, co-founders, former and current directors, and former and current executive officers, including Zachary

Prensky, Andrew Vaino, Ph.D., and Marc Panoff, none of whom were new investors of our Series C preferred stock. We received no consideration as part of the Amended and Restated Royalty Agreements. Pursuant to the Amended and Restated Royalty Agreements, we are obligated to pay royalties to all of the holders in an aggregate amount up to 2.75% of net sales arising from LB-102 worldwide through December 31, 2035. Thereafter, we are obligated to pay royalties to such holders in an aggregate amount up to 3.25% in perpetuity. Net sales are defined in these agreements as the gross payments received on total commercial sales of LB-102 less certain standard deductions, whether received by us or any licensee of LB-102. See the section titled "Royalty Agreements" elsewhere in this Annual Report on Form 10-K for additional information regarding these agreements.

In order to satisfy our obligations to make these payments, if and when they are triggered, we may need to issue equity or convertible debt securities that may cause dilution to our stockholders, or we may use our existing cash and cash equivalents or incur debt obligations to satisfy the payment obligations in cash, which may adversely affect our financial position. In addition, these obligations may impede our ability to raise money in future public offerings of debt or equity securities, to obtain a third-party line of credit, or to license, sell or otherwise monetize our rights in LB-102.

Risks Related to Product Candidate Development and Commercialization

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

LB-102 is in clinical development and its risk of failure is high. It is impossible to predict when or if our product candidate will receive regulatory approval. To obtain the requisite regulatory approvals to commercialize our product candidate, we must demonstrate through lengthy, complex, and expensive clinical trials that our product candidate is safe and effective in patient populations for the relevant indication(s) for use. Preclinical and clinical testing can take many years to complete, and its outcome is inherently uncertain. There is typically a high rate of failure of product candidates proceeding through clinical trials, and failure can occur at any time during the preclinical study or clinical trial process, despite promising preclinical or clinical results. The results of preclinical studies and early clinical trials of our product candidate may not be predictive of the results of later-stage clinical trials, and results in one indication may not be predictive of results to be expected for the same product candidate in another indication. Differences in trial design between early-stage clinical trials and later-stage clinical trials make it difficult to extrapolate the results of earlier clinical trials to later clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unfavorable safety profiles, notwithstanding promising results in earlier trials. For example, emraclidine was previously being developed by Cerevel Therapeutics Holdings, Inc. for the indication of schizophrenia and ceased development due to, among other reasons, not achieving a statistically significant outcome for the primary endpoint in two completed six-week clinical trials. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates achieved promising results have nonetheless failed to obtain marketing approval of such product candidates or, upon commercialization, achieve or maintain positive real-world results. We may be unable to establish clinical endpoints that applicable regulatory authorities would consider clinically meaningful.

Commencing any future clinical trials is subject to finalizing the trial protocol and submitting an IND, or amendments to an existing IND to the FDA or a similar application to initiate a clinical study to a comparable foreign regulatory authority. Even after we make our submission, the FDA or comparable foreign regulatory authorities could disagree that we have satisfied their requirements to commence our clinical trials or disagree with our study design, which may require us to complete additional preclinical studies (including additional carcinogenicity studies in animal models) or amend our protocols or impose stricter conditions on the commencement of clinical trials, which may lead to delays and increase the costs of our preclinical and clinical development programs. The FDA also has the authority to require a panel of experts, referred to as an Advisory Committee, to deliberate on the adequacy of the safety and efficacy data to support approval. The opinion of such an Advisory Committee, although not binding on the FDA, could have a significant impact on our ability to obtain approval of our product candidate in the future. Similar decisions may also be made by foreign regulatory authorities and have a similar impact.

Most product candidates that commence clinical trials are never approved as commercial products and there can be no assurance that any of our current or future clinical trials will ultimately be successful or support the approval of our current or any future product candidates.

We expect to continue to rely on our clinical trial sites and clinical trial teams to ensure the proper and timely conduct of our clinical trials, including the participant enrollment process, and we have limited influence over their performance. In addition, we may in the future enter into collaboration agreements pursuant to which our collaborator would be responsible for clinical development. We or our collaborators may experience delays in initiating or completing clinical trials due to unforeseen events or otherwise, which could delay or prevent our ability to receive marketing approval or commercialize our current and any future product candidates, including:

- regulators, such as the FDA or comparable foreign regulatory authorities, Institutional Review Boards, or IRBs, or ethics committees may impose additional requirements before permitting us to initiate a clinical trial, may not authorize us or our investigators to commence or conduct a clinical trial at a prospective trial site, may not allow us to amend trial protocols, or regulators may disagree as to the design or implementation of our clinical trials and require that we modify or amend our clinical trial protocols or statistical analysis plans;
- we may experience delays in reaching, or fail to reach, agreement on acceptable terms with contract research organizations, or CROs, or with individual clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among trial sites;
- delays in identifying, recruiting, and training suitable clinical investigators;
- IRBs refusing to approve, suspending, or terminating the trial at an investigational site, precluding enrollment of additional patients, or withdrawing their approval of the trial;
- changes or amendments to the clinical trial protocol;
- clinical trial sites may deviate from the trial protocol, fail to ensure the integrity of the data being collected at the site, or drop out of a trial;
- failure by any of our third-party contractors to perform in accordance with good clinical practices, or GCP, requirements or applicable regulatory rules and guidelines in other countries;
- the number of participants required for clinical trials may be larger than we anticipate, we may experience difficulty in finding and enrolling sufficient qualified patients for our trials, enrollment in clinical trials may be slower than we anticipate, or participants may drop out or fail to return for post-treatment follow-up at a higher rate than we anticipate;
- patients may fail to enroll or remain in our trials at the rate we expect, or fail to return for post-treatment follow-up, including patients failing to remain in our trials;
- patients choosing an alternative product for the indications for which we are developing our product candidate, or participating in competing clinical trials;
- the cost of clinical trials may be greater than we anticipate;
- the quality or quantity of data relating to our product candidate or other materials necessary to conduct our clinical trials may be inadequate to initiate or complete a given clinical trial;
- we may experience difficulties in manufacturing, or fail to manufacture, sufficient quantities of our product candidate for use in clinical trials;
- patients experiencing severe or serious unexpected drug-related adverse effects;
- reports from clinical testing conducted by other companies of other therapies in the same class of agents that could be considered similar to our product candidate may raise safety, tolerability, or efficacy concerns about our product candidate;
- we may lack adequate funding to initiate or continue one or more of our clinical trials;
- a facility manufacturing our product candidate 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, or cGMP, regulations or other applicable requirements, or cross-contaminations of product candidates in the manufacturing process;
- changes to our manufacturing processes may be necessary or desired;

- clinical investigators may lose the licenses or permits necessary to perform our clinical trials and may fail to perform our clinical trials on our anticipated schedule or consistent with the clinical trial protocol, GCPs, or other regulatory requirements;
- third-party contractors being unwilling or unable to satisfy their contractual obligations to us in a timely or accurate manner;
- third-party contractors could become debarred or suspended or otherwise penalized by the FDA or other government or regulatory authorities for violations of regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or all of the data produced by such contractors in support of our marketing applications; and
- clinical trials of our product candidate may fail to show appropriate safety, tolerability, or efficacy, may produce negative or inconclusive results, or may otherwise fail to improve on the existing standard of care, and we may decide, or regulators may require us, to conduct additional clinical trials or we may decide to abandon product development programs.

Clinical trials must be conducted in accordance with the FDA and other applicable regulatory authorities' legal requirements, regulations, and guidelines, and remain subject to oversight by these governmental agencies as well as ethics committees or IRBs responsible for overseeing the conduct of clinical trials and ensuring the welfare of patients participating in the research. We could encounter delays if a clinical trial is suspended or terminated by us, the IRBs of the institutions in which such trials are being conducted, the FDA or comparable foreign regulatory authorities, or the Data Safety Monitoring Board, for such trial. A suspension or termination may be imposed due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical trial protocols, adverse findings from inspection of the clinical trial operations or trial site by the FDA or comparable foreign regulatory authorities, unforeseen safety issues or adverse side effects, failure to establish or achieve clinically meaningful trial endpoints, changes in governmental regulations or administrative actions, or lack of adequate funding to continue the clinical trial. 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 regulators or to IRBs for reexamination, which may impact the costs, timing, or successful completion of a clinical trial. Clinical trials may also be delayed or terminated as a result of ambiguous or negative interim results.

Many of the factors that cause, or lead to, a delay in the commencement or completion of, or the termination or suspension of, clinical trials may also ultimately lead to the denial of regulatory approval of our product candidate. Further, the FDA may disagree with our interpretation of data from clinical trials, or may change the requirements for approval even after it has reviewed and commented on the design for our clinical trials.

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

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

Even if we complete the necessary preclinical studies and clinical trials, the marketing approval process is expensive, time-consuming, and uncertain and may prevent us or any future collaboration partners from obtaining approvals for the commercialization of our product candidate.

Any product candidate we may develop and the activities associated with their development and commercialization, including their design, testing, manufacture, recordkeeping, labeling, storage, approval, advertising, promotion, import, export, marketing, and distribution, are subject to comprehensive regulation by the FDA and other regulatory authorities in the United States and by comparable foreign regulatory authorities. Failure to obtain marketing approval for a product

candidate will prevent us from commercializing the product candidate in a given jurisdiction. We have not received approval to market any product candidates from regulatory authorities in any jurisdiction and none of the product candidates we may seek to develop in the future may ever obtain regulatory approval. We have no experience in filing and supporting the applications necessary to gain marketing approvals. Although we believe that we have the capabilities to conduct preclinical studies and clinical trials and complete these applications using our internal resources and the necessary personnel we intend to hire in the future, we selectively employ and may in the future rely on CRO or consultants to assist us in this process. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. The FDA may also not agree with our determination that our Phase 2 acute schizophrenia trial may serve as one of the two pivotal trials required for approval of an NDA in the United States. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Any product candidates we develop may not be effective, may be only moderately effective, or may prove to have undesirable or unintended side effects, toxicities, or other characteristics that may preclude our ability to obtain marketing approval for such product candidates or prevent or limit future commercial use.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive, often takes many years following the commencement of clinical trials, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity, and novelty of the product candidates involved, as well as the target indications and patient populations. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. Prior to obtaining approval to commercialize a product candidate in the U.S. or abroad, we must demonstrate with substantial evidence from adequate and well-controlled clinical trials, and to the satisfaction of the FDA or comparable foreign regulatory authorities, that such product candidates are safe and effective for their intended uses. The FDA and comparable foreign regulatory authorities have substantial discretion in the approval process and may delay, limit, or deny approval of a product candidate for many reasons, or may decide that our data are insufficient for approval and require additional preclinical, clinical, or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit, or prevent marketing approval of a product candidate. Despite the time and expense invested in clinical development of product candidates, regulatory approval of a product candidate is never guaranteed. Of the large number of drugs in development, only a small percentage successfully complete the FDA or foreign regulatory approval processes and are commercialized.

With respect to foreign markets, approval procedures vary among countries and, in addition to the foregoing risks, may involve additional product testing, administrative review periods, and agreements with pricing authorities.

Even if we eventually complete clinical trials and receive approval of an NDA or comparable foreign marketing application for our product candidate, the FDA or comparable foreign regulatory authority may grant approval contingent on the performance of costly additional clinical trials and/or the implementation of REMS, which may be required because the FDA believes it is necessary to ensure safe use of the product after approval.
If we experience delays in obtaining approval or if we fail to obtain approval of any product candidates we may develop, the commercial prospects for those product candidates, including for other indications, may be harmed, and our ability to generate revenues will be materially impaired.

Even if our product candidate receives regulatory approval, it may fail to achieve the degree of market acceptance by physicians, patients, and others in the medical community necessary for commercial success, in which case we may not generate significant revenues or become profitable.

We have never commercialized a product candidate for any indication. Even if our product candidate is approved by the appropriate regulatory authorities for marketing and sale, our product candidate may not gain acceptance among physicians, patients, third-party payors, and others in the medical community. If our product candidate for which we obtain regulatory approval does not gain an adequate level of market acceptance, we may not generate sufficient product revenue or become profitable. Further, the number of patients that our product candidate is designed to treat may be smaller than expected.

The degree of market acceptance of our product candidate, if approved and commercialized, will depend on a number of factors, some of which are beyond our control, including:

- the pricing and cost-effectiveness of our product candidate, as well as the ease of administration, time burden, and market acceptance;
- the safety, efficacy, and tolerability of our product candidate;
- acceptance of our approach to precision psychiatry by patients, the medical community, and third-party payors;
- changes in the standard of care for targeted indications and the reluctance of physicians to switch their patients' current standard of care;
- the reluctance of patients to switch from their existing therapy regardless of the safety and efficacy of newer products;
- the clinical indications for which our product is approved and the scope of efficacy/safety claims that we may make for the product;
- any restrictions on the use of our product, and the prevalence and severity of any adverse effects;
- any distribution and use restrictions imposed by the FDA as part of a mandatory REMS with respect to such product candidate or to which we agree under a voluntary risk management plan;
- the availability of adequate coverage and reimbursement by third parties, such as insurance companies and other healthcare payors, and by government healthcare programs, including Medicare and Medicaid;
- the willingness of patients to pay all, or a portion of, out-of-pocket costs associated with our products in the absence of sufficient third-party coverage and adequate reimbursement;
- the extent and strength of our marketing and distribution of such product candidate;
- the timing of market introduction of such product candidate, as well as competitive products;
- our ability to offer our product candidate for sale at competitive prices;
- the competitiveness of existing approved therapies;
- adverse publicity about our product or favorable publicity about competitive products; and
- potential product liability claims.

In addition, our lead product candidate, LB-102, is an *N*-methylated version of amisulpride, a drug already approved in certain parts of Europe for the treatment of schizophrenia, predominantly negative symptoms of schizophrenia and dysthymia. While we are developing LB-102 for acute schizophrenia initially in the United States and potentially in other jurisdictions where amisulpride is not approved, we currently plan to develop LB-102 to treat bipolar depression and adjunctive MDD globally and if there is a recall, safety concern, or adverse regulatory action with respect to amisulpride in Europe, it could prevent us from achieving or maintaining market acceptance of LB-102 or otherwise adversely affect our ability to successfully commercialize LB-102. Furthermore, although LB-102 is structurally similar to amisulpride, which is an approved product in many countries outside of the United States, there can be no assurance that our ongoing and future clinical trials will show similar results with respect to safety and/or efficacy.

Our efforts to educate the medical community and third-party payors about the benefits of our product candidate may require significant resources and may never be successful. Even if our product candidate, if approved, is safe and effective for its approved indications, physicians and patients may not immediately be receptive to such product candidate and may be slow to adopt it as an accepted treatment for the approved indications. If our current or future product candidates are approved, but do not achieve an adequate level of acceptance among physicians, patients, and third-party payors, we may not generate meaningful revenue from our product candidate and may never become profitable.

We may find it difficult to enroll patients in our clinical trials. If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

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 and enroll 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 candidate if we are unable to identify and enroll a sufficient number of eligible patients to participate in these trials to such trial's conclusion as required by the FDA or comparable foreign regulatory authorities. Patient enrollment is affected by many factors including the size and nature of the patient population, competing clinical trials in the same or similar indications or at the same trial site, the severity of the disease or condition under investigation, the availability and efficacy of approved drugs and diagnostics for the disease or condition under investigation, the number and location of clinical sites, the proximity of patients to clinical sites, willingness of patients to participate in a decentralized clinical trial that may involve remote monitoring technologies, the inclusion and exclusion criteria for the trial, perceived risks and benefits of the product candidate under study, the design of the clinical trial, continued enrollment of prospective patients by clinical trial sites, the risk that enrolled patients will not complete a clinical trial, our ability to recruit clinical trial investigators with the appropriate competencies and experience, efforts to facilitate timely enrollment in clinical trials, patient referral practices of physicians, the ability to monitor patients adequately during and after treatment, competing clinical trials, and clinicians' and patients' perceptions as to the potential advantages and risks of the product candidate being studied in relation to other available therapies, including any new products that may be approved for, or any product candidates under investigation for, the indications we are investigating. Clinical trial recruitment and enrollment activities may also be delayed as a result of macro-factors such as public health emergencies or pandemics, natural disasters, acts of terror or war, or staffing shortages.

We will be required to identify and enroll a sufficient number of patients for each of our clinical trials. We may not be able to initiate or continue clinical trials if we are unable to locate a sufficient number of eligible patients to participate in the clinical trials required by the FDA or comparable foreign regulatory authorities. In addition, the process of finding eligible patients may prove costly.

Historically, clinical trials in acute schizophrenia, bipolar depression, and adjunctive MDD have experienced significant participant withdrawals or discontinuations. There is no guarantee that our estimated withdrawal rate in any of our clinical trials will be accurate, and if we experience a withdrawal rate larger than expected, this may compromise the quality of our data. Withdrawal of participants from our clinical trials, including participants in any control groups, may compromise the quality of our data. Even if we are able to enroll a sufficient number of participants in our clinical trials, we may have difficulty maintaining enrollment of such patients, and delays in enrollment may result in increased costs or may affect the timing or outcome of our clinical trials. Any of these conditions may negatively impact our ability to complete such trials or include results from such trials in regulatory submissions, which could adversely affect our ability to advance the development of our product candidate. Additionally, participants with neuropsychiatric disorders, including schizophrenia, constitute a vulnerable patient population and may withdraw from the clinical trial if they are not experiencing improvement in their underlying disease or condition or if they experience other difficulties or issues relating to their underlying disease or condition or otherwise.

Further, other biopharmaceutical companies targeting these same diseases are recruiting clinical trial patients from similar patient populations, which may make it more difficult to fully enroll any clinical trials. Our inability to enroll a sufficient number of patients for any of our future clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. In addition, we expect to rely on 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 have limited influence over their actual performance.

We cannot assure you that our assumptions used in determining expected clinical trial timelines are correct or that we will not experience delays in enrollment, which would result in the delay of completion of such trials beyond our expected timelines.

Use of our product candidate could be associated with adverse side effects, adverse events, or other safety risks, which could delay or preclude the candidate's approval, cause us to suspend or discontinue clinical trials, cause us to abandon the product candidate, limit the commercial profile of any future approved product, or result in other

significant negative consequences that could severely harm our business, prospects, operating results, and financial condition.

Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics related to our product candidate. Undesirable side effects caused by our product candidate could cause us, the IRB, or regulatory authorities to interrupt, delay, or halt clinical trials or cause the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities, or, if such product candidate is approved, result in a more restrictive label and other post-approval requirements. Any treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial or could result in potential product liability claims. Any of these occurrences may harm our business, financial condition, and prospects significantly.

If our product candidate is associated with undesirable side effects or has unexpected characteristics in clinical trials, we may need to interrupt, delay, or abandon their development or limit development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe, or more acceptable from a risk-benefit perspective. To date, treatment emergent adverse events, or TEAEs, from our Phase 1 and Phase 2 trials were generally mild or moderate. TEAEs included events typically associated with dopamine antagonists. In the Phase 2 trial the most frequently occurring TEAEs were insomnia, headache, anxiety and agitation. Low rates of adverse events associated with EPS and modest increases in QT prolongation were observed. Consistent with other antipsychotics, use of LB-102 resulted in elevated serum prolactin levels, but these elevations were associated with very few adverse events associated with that increase. In our Phase 2 acute schizophrenia trial, 10 participants reported TEAEs leading to withdrawal, including two in each of the placebo and 50 mg cohorts, as well as three in each of the 75 mg and 100 mg cohorts. There were five reported serious adverse events, or SAEs, overall with two SAEs in the placebo cohort (psychotic disorder and death), one SAE in the 50 mg cohort (suicidal ideation—deemed possibly related to treatment), one SAE in the 75 mg cohort (dystonia—deemed possibly related to treatment) and one SAE in the 100 mg cohort (psychotic disorder—deemed not related to treatment). The incidence of TEAEs was similar across groups, with most events being mild or moderate.

Patients in our ongoing and planned clinical trials may in the future suffer significant adverse events or other side effects not observed in our preclinical studies or previous clinical trials. Even if such side effects do not preclude the product candidate from obtaining or maintaining regulatory approval, undesirable side effects may inhibit market acceptance due to tolerability concerns as compared to other available therapies. Any of these developments could materially harm our business, financial condition, and prospects.

Additionally, if our product candidate receives regulatory approval, and we or others later identify undesirable side effects caused by such product, a number of potentially significant negative consequences could result. For example, the FDA could require us to adopt a Risk Evaluation and Mitigation Strategy, or REMS, to ensure that the benefits of treatment with such product candidate outweigh the risks for each potential patient, which may include, among other things, a communication plan to health care practitioners, patient education, extensive patient monitoring, or distribution systems and processes that are highly controlled, restrictive, and more costly than what is typical for the industry. Other potentially significant negative consequences associated with post-marketing identification of adverse events or other safety risks include:

- we may be required to suspend marketing of a product, or we may decide to remove such product from the marketplace;
- regulatory authorities may withdraw or modify their approvals of a product;
- regulatory authorities may require additional warnings or new contraindications on the label, or may limit access of a product to selective specialized centers with additional safety reporting and with requirements that patients be geographically close to these centers for all or part of their treatment;
- we may be required to create a medication guide outlining the risks of a product for patients, or to conduct post-marketing studies;
- we may be required to change the way a product is distributed or administered;
- we could be subject to fines, injunctions, or the imposition of criminal or civil penalties, or be sued and held liable for harm caused to subjects or patients; and
- a product may become less competitive, and our reputation may suffer.

In addition, participants with neuropsychiatric disorders, including schizophrenia, bipolar depression and major depressive disorder, constitute a vulnerable patient population, and any adverse side effects or adverse events may be exacerbated in such patient population. Any of these events could diminish the usage or otherwise limit the commercial success of our product candidate and prevent us from achieving or maintaining market acceptance of our product candidate, if approved by the FDA or other regulatory authorities.

We have never commercialized a product candidate and may experience delays or unexpected difficulties in obtaining, or fail to obtain, regulatory approval for our product candidate.

We have never obtained regulatory approval for, or commercialized, a drug product in the United States or elsewhere.

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

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials, such as our determination that our Phase 2 acute schizophrenia trial may serve as one of the two pivotal trials required for approval of an NDA in the United States;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that our product candidate is safe and effective for any of their proposed indications;
- we may have negative or ambiguous results from our clinical trials, or results may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- 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;
- regulatory authorities may not accept clinical data from trials that are conducted at clinical facilities or in countries where the standard of care is potentially different from that of their own country;
- serious and unexpected drug-related side effects may be experienced by participants in our clinical trials or by individuals using drugs similar to our product candidate;
- 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 candidate may not be sufficient to the satisfaction of the FDA or comparable foreign regulatory authorities to support the submission of an NDA, or other comparable submission in foreign jurisdictions or to obtain regulatory approval in the United States or elsewhere, and such authorities may impose requirements for additional preclinical studies or clinical trials;
- such authorities may disagree with us regarding the formulation, labeling, and/or release/stability specifications of our product candidate;
- approval may be granted only for indications that are significantly more limited than those sought by us, and/or may include significant restrictions on distribution and use;
- regulatory authorities may not accept a submission due to, among other reasons, the content or formatting of the submission; and
- the FDA or comparable foreign regulatory authorities may find deficiencies in or fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies.

In addition, our lead product candidate, LB-102, is an *N*-methylated version of amisulpride, a drug already approved in certain parts of Europe for the treatment of schizophrenia, predominantly negative symptoms of schizophrenia and dysthymia. While we are developing LB-102 for acute schizophrenia initially in the United States and potentially in other jurisdictions where amisulpride is not approved, we currently plan to develop LB-102 to treat bipolar depression and adjunctive MDD globally and if there is a recall, safety concern, or adverse regulatory action with respect to amisulpride in Europe, it could adversely affect our ability to obtain regulatory approval for LB-102.

Finally, the FDA and comparable foreign regulatory authorities may change their approval policies and new regulations may be enacted, which could delay or prevent our ability to obtain approval. If our product candidate fails to achieve regulatory approval due to the above factors, or otherwise, any such failure would adversely affect our business, results of operations, and financial condition. In addition, difficulties in obtaining approval of a product candidate in any of the initial indications for which we are developing it could adversely affect our efforts to seek approval from regulatory authorities for other indications.

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

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

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

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions, or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and could adversely affect the success of our business. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure.

If the interim, top-line or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidate may be harmed, which could harm our business, financial condition, results of operations, and prospects. Further, disclosure of interim, top-line, or preliminary data by us or by our competitors could result in volatility in the price of our common stock.

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

If we fail to develop and commercialize our current product candidate for additional indications or fail to discover, develop, and commercialize other product candidates, we may be unable to grow our business and our ability to achieve our strategic objectives would be impaired.

Although the development and commercialization of our current product candidate for the treatment of schizophrenia, bipolar depression and adjunctive MDD is our primary focus, as part of our longer-term growth strategy, we plan to evaluate our current product candidates in other indications (such as negative symptoms of schizophrenia, Alzheimer's disease psychosis and agitation, and other neuropsychiatric diseases) and develop other product candidates. We intend to evaluate internal opportunities from our current product candidate or other potential product candidates and also may choose to in-license or acquire other product candidates as well as commercial products to treat patients suffering from other disorders with significant unmet medical needs and limited treatment options. These other potential product candidates will require additional, time-consuming development efforts prior to commercial sale, including preclinical

studies, clinical trials, and approval by the FDA and/or comparable foreign regulatory authorities. All product candidates are prone to the risks of failure that are inherent in pharmaceutical product development, including the possibility that the product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, we cannot assure you that any such products, if approved, will be manufactured or produced economically, successfully commercialized, or widely accepted in the marketplace, or be more effective than other commercially available alternatives.

Research programs to identify product candidates require substantial technical, financial, and human resources, whether or not any product candidates are ultimately identified. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for many reasons, including the following:

- the research methodology used may not be successful in identifying potential product candidates;
- competitors may develop alternatives that render our product candidate(s) obsolete;
- product candidates that we develop may nevertheless be covered by third parties' patents or other exclusive rights;
- a product candidate may, on further study, be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and
- a product candidate may not be accepted as safe and effective by patients, the medical community, or third-party payors.

If we are unsuccessful in identifying and developing additional product candidates, our potential for growth and achieving our strategic objectives may be impaired.

We may expend our resources to pursue a particular product candidate or indication and forgo the opportunity to capitalize on product candidates or indications that may ultimately be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we intend to focus on developing product candidate for specific indications that we identify as most likely to succeed, in terms of both their potential for regulatory approval and commercialization. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that may prove to have greater commercial potential.

Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on research and development programs and product candidate for specific indications may not yield any commercially viable product candidate. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing, or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to the product candidate.

Obtaining and maintaining regulatory approval of LB-102 or any future product candidates we may develop in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of such product candidate in other jurisdictions.

We may seek regulatory approval for LB-102 or any future product candidates we may develop outside the United States. Foreign regulatory authorities have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining and maintaining regulatory approval of LB-102 or any future product candidates we may develop in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction. However, a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions also must approve the manufacturing, marketing, and promotion of the product candidate in those jurisdictions. 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 addition, in some 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 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 fail to comply with the regulatory requirements in international markets and/or receive and maintain applicable marketing approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of our product candidate will be harmed, which could adversely affect our business, results of operations, and financial condition.

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

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

Third-party payors increasingly are challenging prices charged for pharmaceutical products and services, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs when an equivalent generic drug or a less expensive therapy is available. It is possible that a third-party payor may consider our product candidate as substitutable and only offer to reimburse patients for the less expensive product. These payors may deny or revoke the reimbursement status of a given product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in product development. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our products, if approved, and may not be able to obtain a satisfactory financial return on products that we may develop.

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

Obtaining and maintaining reimbursement status is time-consuming, costly, and uncertain. The Medicare and Medicaid programs increasingly are used as models for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs. However, no uniform policy for coverage and reimbursement for products exists among third-party payors in the United States. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases at short notice, and we believe that changes in these rules and regulations are likely.

Under currently applicable U.S. law, certain products not usually self-administered (including injectable drugs) may be eligible for coverage under Medicare through Medicare Part B. Medicare Part B is part of original Medicare, the federal health care program that provides health care benefits to the aged and disabled, and covers outpatient services and

supplies, including certain biopharmaceutical products, that are medically necessary to treat a beneficiary's health condition. As a condition of receiving Medicare Part B reimbursement for a manufacturer's eligible drugs, the manufacturer is required to participate in other government healthcare programs, including the Medicaid Drug Rebate Program and the 340B Drug Pricing Program. The Medicaid Drug Rebate Program requires pharmaceutical manufacturers to enter into and have in effect a national rebate agreement with the U.S. Department of Health and Human Services, or HHS, as a condition for states to receive federal matching funds for the manufacturer's outpatient drugs furnished to Medicaid patients. Under the 340B Drug Pricing Program, the manufacturer must extend discounts to entities that participate in the program.

Additionally, the containment of healthcare costs has become a priority of federal, state and foreign governments. For example, the U.S. Department of Health and Human Services, or HHS, imposes rebates on many Medicare Part B and Medicare Part D products to penalize price increases that outpace inflation on an annual basis. HHS has also been empowered to negotiate the price of certain single-source drugs that have been on the market for at least seven (7) years covered under Medicare as part of the Medicare Drug Price Negotiation Program. Each year up to twenty (20) products will be selected by HHS for the Medicare Drug Price Negotiation Program. Products subject to the Medicare Drug Price Negotiation Program are expected to experience a significant reduction in reimbursement from the Medicare program on a per unit basis.

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

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

Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay.

As product candidates are developed through pre-clinical to late-stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation (including raw materials and starting materials), are altered in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidate to perform differently and affect the results of planned clinical trials or future clinical trials to be conducted with the altered materials. Such changes may also require additional testing, notification to the FDA or comparable foreign regulatory authorities or approval from the FDA or comparable foreign regulatory authorities. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidate and/or jeopardize our ability to commence product sales and generate revenue.

We may conduct certain of our clinical trials for our product candidate outside of the United States in the future. However, the FDA may not accept data from such trials, in which case our development plans may be delayed, which could materially harm our business.

Although we currently conduct all of our clinical trials in the United States, in the future we may conduct one or more of our clinical trials for our product candidate outside the United States. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of these data is subject to certain conditions imposed by the FDA.

For example, to accept data from a clinical trial that was conducted only at sites outside of the United States and not subject to an IND, the FDA requires such clinical trial to have been conducted in accordance with GCPs, and the FDA must be able to validate the data from the clinical trial through an on-site inspection if the FDA deems such inspection necessary. In cases where data from foreign clinical trials are intended to serve as the sole basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice; (ii) the trials were performed by clinical investigators of recognized competence and pursuant to GCP regulations; and (iii) the data may be considered valid without the need for an on-site inspection by the FDA, or if the FDA considers such inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. For studies not subject to an IND, the FDA generally does not review clinical protocols for the studies, and therefore there is an additional potential risk that the FDA could determine that the study design, protocol, and/or results from a non-U.S. clinical trial were inadequate for the purposes we intend, which could require us to conduct additional clinical trials. Many foreign regulatory authorities have similar requirements for clinical data gathered outside of their respective jurisdictions. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance the FDA or any comparable foreign regulatory authority will accept data from clinical trials conducted outside of the United States or the relevant jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept data from our clinical trials of our product candidate, it may result in the need for additional clinical trials, which would be costly and time-consuming and could delay or permanently halt our development of our product candidate.

Risks Related to Our Business and Operations

Neuroscience drug development is a field that has seen limited success. The ability to successfully develop drugs in this field is difficult and is subject to a number of unique challenges.

Drug development in the field of brain diseases, neuropsychiatric disorders and neurodegenerative diseases in particular, has seen limited success historically. Developing a successful product candidate for treatment of these brain diseases is difficult and subjects us to a number of unique challenges, including obtaining regulatory approval from the FDA and other regulatory authorities who have only a limited set of precedents to rely on.

We intend to work closely with the FDA and comparable foreign regulatory authorities to perform the requisite scientific analyses and evaluation in an effort to obtain regulatory approval for our product candidate; however, the process of developing our product candidate may be more complex and time-consuming relative to other more well-known approaches to drug development. We cannot be certain that our approach will lead to the development of a product candidate that effectively and safely addresses the underlying brain diseases.

Moreover, given the history of clinical failures in this field, future clinical or regulatory failures by us or others may result in further negative perception of the likelihood of success in this field, which may significantly and adversely affect the market price of our common stock.

Our business depends on the success of our product candidate. If we are ultimately unable to successfully commercialize our product candidate, or experience significant delays in doing so, our business will be materially harmed.

We currently have no products approved for commercial sale or for which regulatory approval to market has been sought. We have invested a significant portion of our efforts and financial resources in the development of our product candidate, which is still in clinical development, and expect that we will continue to invest heavily in such product candidate, as well as in any future product candidates we may develop. Our business and our ability to generate revenue, which we do not expect will occur for many years, if ever, are substantially dependent on our ability to develop, obtain regulatory approval for, and then successfully commercialize LB-102, which may never occur.

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

- achieve market acceptance of our future approved product by patients, the medical community, and third-party payors;

- create market demand for our approved product through our own marketing and sales activities, and any other arrangements to promote the approved product that we may otherwise establish in the future;
- receive regulatory approval for the targeted patient populations and efficacy/safety claims that are necessary or desirable for successful marketing;
- price our product competitively such that third-party and government reimbursement permits broad product adoption;
- manufacture our product candidate through contract development and manufacturing organizations, or CDMOs, in sufficient quantities and at acceptable quality and manufacturing cost to meet commercial demand at launch and thereafter;
- establish and maintain agreements with wholesalers, distributors, pharmacies, and group purchasing organizations on commercially reasonable terms;
- obtain, maintain, protect, and enforce patent and other intellectual property protection and regulatory exclusivity for our product, if approved;
- maintain compliance with applicable laws, regulations, and guidance specific to commercialization including interactions with health care professionals, patient advocacy groups, and communication of health care economic information to payors and formularies; and
- assure that our product candidate, if approved, will be used as directed and that additional unexpected safety risks will not arise.

We rely on, and intend to continue to rely on, our internal clinical development expertise to conduct our current and future clinical trials. This model includes internal teams and systems as well as external vendors and CROs to comprise a full clinical trial team. If our clinical trial team does not comply with applicable regulatory requirements, meet expected deadlines, or run trials effectively, our development programs and our ability to seek or obtain regulatory approval for or commercialize our product candidate may be delayed.

We conduct much of our clinical trial work (e.g., clinical and medical monitoring, data management, and project management) with CROs as well as utilizing internal personnel to augment and oversee our CROs. Although we believe that our CROs currently have the capabilities to conduct clinical trials in collaboration with our internal staff, we may need to rely on additional third party CROs to conduct clinical trials if our internal and existing CRO capabilities cannot scale as we work to progress LB-102 through development, as we potentially expand our product candidate portfolio, or if we do not have sufficient personnel to support our clinical program. Our failure or the failure of any CROs we may employ to conduct the trials in compliance with FDA regulations could result in a delay or failure in obtaining FDA approval and could require us to repeat any preclinical studies or clinical trials we or the CRO administered.

Further, as part of our engagement with CROs, we have to negotiate budgets and contracts with them and/or each trial site, which may result in delays to our development timelines and increased costs. If any of our relationships with CROs and/or trial sites terminate, we may not be able to enter into arrangements with alternative trial sites or do so on commercially reasonable terms. Switching or adding additional trial sites can also involve additional costs and requires time and focus of our clinical trial operations management team.

Competitive products may reduce or eliminate the commercial opportunity for our product candidate for our current or future indications. If our competitors develop technologies or product candidates more rapidly than we do, or their technologies are more effective or safer than ours, our ability to develop and successfully commercialize our current products may be adversely affected.

The biopharmaceutical industry is characterized by rapid innovation and intense competition. While we believe that our clinical program provides us with competitive advantages, we face competition from multiple biopharmaceutical and biotechnology companies that are similarly working to develop therapeutics targeting neuropsychiatry and, central nervous system, or CNS, disorders, as well as from academic institutions, governmental agencies, and public and private research institutions. Many of our potential competitors, either alone or with collaboration partners, have significantly greater financial resources than we do, as well as equal or greater experience in the discovery and development of product candidates, obtaining FDA and other regulatory approvals of products, and the commercialization of those products. Accordingly, our potential competitors may be more successful than we are in achieving regulatory approvals

and commercializing their products. We anticipate that we will face intense and increasing competition from existing, approved drugs, as well as new drugs entering the market and emerging technologies that become available.

We are developing LB-102 for the treatment of schizophrenia, bipolar depression, and adjunctive MDD. While there remains significant unmet need in these indications, we believe LB-102, if approved, may face competition from product candidates also being developed for treatment of schizophrenia, bipolar depression, and adjunctive MDD.

We believe the key competitive factors affecting the success of our product candidate that we develop to address schizophrenia, bipolar depression, adjunctive MDD, and other CNS disorders, if approved, are likely to be efficacy, safety, convenience, price, the level of generic competition, and the availability of reimbursement from government and other third-party payors. Our profitability and financial position will suffer if our product candidate receives regulatory approval but cannot compete effectively in the marketplace.

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

As of December 31, 2025, we had 27 employees. As our development and commercialization plans and strategies develop, and as we transition into operating as a public company, we expect to expand our employee base for managerial, operational, financial, and other resources. In addition, we have limited experience in manufacturing and commercialization. As our product candidate enters and advances through clinical trials, we will need to expand our development and regulatory capabilities and contract with other organizations to provide manufacturing and other capabilities for us. In the future, we expect to have to manage additional relationships with collaborators or partners, suppliers and other organizations. Our ability to manage our operations and future growth will require us to continue to improve our operational, financial, and management controls, reporting systems and procedures, which may lead to significant costs and may divert management attention. We may not be able to implement improvements to our management information and control systems in an efficient or timely manner and may discover deficiencies in existing systems and controls.

Our inability to successfully manage our growth and expand our operations could adversely affect our business, financial condition, results of operations, and prospects.

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

Our success depends in part on our continued ability to attract, retain, and motivate highly qualified management, clinical, and scientific personnel. We are highly dependent upon our Chief Executive Officer, Heather Turner, and other members of our management team. The loss of services of any of these individuals could delay or prevent the successful development and commercialization of our product candidate. Although we have executed employment agreements or offer letters with each member of our senior management team, these agreements are terminable at will with or without notice and, therefore, we may not be able to retain their services as expected.

Additionally, in light of our insourced clinical trial model, we are heavily reliant on the expertise of our clinical trial team, and the loss of even a small number of those employees could have a significant adverse impact on our ability to conduct our clinical trials in a compliant and timely manner. Additionally, as we expand our clinical trial operations, or if we experience turnover within our clinical trial team, even if we are able to recruit qualified personnel to support our insourced clinical trial model, the onboarding and integration process takes time and can result in delays to our clinical development timeline.

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

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

We are exposed to the risk of employee fraud or other illegal activity by our current and any future employees, independent contractors, consultants, commercial partners, CROs, CDMOs, and vendors. Misconduct by these parties could include intentional, reckless, and/or negligent conduct that fails to comply with FDA or other regulations, provide true, complete and accurate information to the FDA, European Medicines Agency, and other comparable foreign regulatory authorities, comply with manufacturing standards we may establish, comply with healthcare fraud and abuse laws and regulations, report financial information or data accurately, or disclose unauthorized activities to us. If we obtain FDA approval of our product candidate and begin commercializing the product in the United States, our potential exposure under these laws will increase significantly, and our costs associated with compliance with these laws are likely to increase. In particular, sales, marketing, and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing, and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs, and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a material and adverse effect on our business, financial condition, results of operations, and prospects, including the imposition of significant civil, criminal, and administrative penalties, damages, fines, disgorgement, imprisonment, the curtailment or restructuring of our operations, loss of eligibility to obtain approvals from the FDA, exclusion from participation in government contracting, healthcare reimbursement or other government programs, including Medicare and Medicaid, integrity oversight and reporting obligations, or reputational harm.

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

As we conduct clinical trials of our current or future product candidates, we are exposed to significant product liability risks inherent in the development, testing, manufacturing, and marketing of new treatments. Product liability claims could delay or prevent completion of our development programs. If we succeed in obtaining approval for, and marketing products, such claims or certain adverse event trends could result in an investigation by the FDA, comparable foreign regulatory authorities, or other regulators into the safety and efficacy of our future approved products, our manufacturing processes and facilities, or our marketing programs and potentially a recall of our products or more serious enforcement action, limitations on the approved indications for which they may be used, or suspension or withdrawal of approvals. Regardless of the merits or eventual outcome, liability claims may also result in decreased demand for our future approved products, termination of clinical trial sites or entire trial programs, withdrawal of clinical trial participants, injury to our reputation and significant negative media attention, significant costs to defend the related litigation, a diversion of management's time and our resources from our business operations, substantial monetary awards to trial participants or patients, loss of revenue, the inability to commercialize any products that we may develop, and a decline in our stock price. We may need to obtain higher levels of product liability insurance for later stages of clinical development or marketing our product candidate. Any insurance we may obtain may not provide sufficient coverage against potential liabilities. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to obtain sufficient insurance at a reasonable cost to protect us against losses caused by product liability claims that could adversely affect our business, financial condition, results of operations, and prospects.

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

If our information technology systems or those of third parties with whom we work, or our data are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited

to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse consequences.

In the ordinary course of business, we and the third parties with whom we work, collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share, or collectively, process, personal data and other sensitive information, including proprietary and confidential business information, trade secrets, intellectual property, information we collect about trial participants in connection with clinical trials, and sensitive third-party information, or collectively, sensitive data. As a result, we and the third parties with whom we work face a variety of evolving threats that could cause security incidents. Cyber-attacks, malicious internet-based activity, online and offline fraud, and other similar activities threaten the confidentiality, integrity, and availability of our sensitive data and information technology systems, and those of the third parties with whom we work. Such threats are prevalent and continue to rise, are increasingly difficult to detect, and come from a variety of sources, including traditional computer "hackers," threat actors, "hacktivists," organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation-state-supported actors.

Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties upon with whom we work may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our services.

We and the third parties with whom we work are subject to a variety of evolving threats, including but not limited to social-engineering attacks (including through deep fakes, which may be increasingly more difficult to identify as fake, and phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks, credential stuffing, credential harvesting, personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, attacks enhanced or facilitated by artificial intelligence, or AI, telecommunications failures, earthquakes, fires, floods, and other similar threats.

In particular, severe ransomware attacks are becoming increasingly prevalent and can lead to significant interruptions in our operations, ability to provide our products or services, loss of sensitive data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments.

It may be difficult and/or costly to detect, investigate, mitigate, contain, and remediate a security incident. Our efforts to do so may not be successful. Actions taken by us or the third parties with whom we work to detect, investigate, mitigate, contain, and remediate a security incident could result in outages, data losses, and disruptions of our business. Threat actors may also gain access to other networks and systems after a compromise of our networks and systems. For example, threat actors may use an initial compromise of one part of our environment (or that of third parties with whom we work) to gain access to other parts of our environment, or leverage a compromise of the relevant networks or systems to gain access to the networks or systems of third parties with whom we work, such as through phishing or supply chain attacks.

Remote work has increased risks to our information technology systems and data, as more of our personnel utilize network connections, computers, and devices outside our premises or network, including working at home, while in transit or in public locations. Additionally, future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

In addition, our reliance on third parties could introduce new cybersecurity risks and vulnerabilities, including supply-chain attacks, and other threats to our business operations. We rely on various third parties and technologies to operate critical business systems to process sensitive data in a variety of contexts, including, without limitation, cloud-based infrastructure, data center facilities, encryption and authentication technology, personnel email, and other functions. We also rely on third parties to provide other products, services, parts, or otherwise to operate our business, including with

respect to our cybersecurity infrastructure. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If the third parties with whom we work experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if such third parties fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or that of the third parties with whom we work have not been compromised.

While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We may not, however, detect and remediate all such vulnerabilities including on a timely basis. Further, we may experience delays in developing and deploying remedial measures and patches designed to address identified vulnerabilities. Vulnerabilities could be exploited and result in a security incident.

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

We may expend significant resources or modify our business activities (including our clinical trial activities) to try to protect against security incidents. Additionally, certain data privacy and security obligations may require us to implement and maintain specific security measures or industry-standard or reasonable security measures to protect our information technology systems and sensitive data.

Applicable data privacy and security obligations may require us, or we may voluntarily choose, to notify relevant stakeholders, including affected individuals, regulators, and investors, of security incidents, or take other actions, such as providing credit monitoring and identity theft protection services. Such disclosures and related actions can be costly, and the disclosure or the failure to comply with such applicable requirements could lead to adverse consequences.

If we (or a third party with whom we work) experience a security incident or are perceived to have experienced a security incident, we may experience material adverse consequences, such as government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive data (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; diversion of management attention; interruptions in our operations (including availability of data); financial loss; and other similar harms. Security incidents and attendant material consequences may negatively impact our ability to grow and operate our business.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage, if any, will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

In addition to experiencing a security incident, third parties may gather, collect, or infer sensitive data about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position. Additionally, sensitive data that we possess could be leaked, disclosed, or revealed as a result of or in connection with our personnel's or vendors' use of generative AI technologies.

We have identified material weaknesses in our internal control over financial reporting. If we fail to remediate these material weaknesses, or if we experience additional material weaknesses in the future or otherwise fail to maintain effective internal control over financial reporting in the future, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our common stock.

As of December 31, 2025, although we made significant improvement throughout the year, we had limited accounting personnel and other resources with which to address our internal control over financial reporting. In connection with the

preparation of our financial statements for the year ended December 31, 2025, material weaknesses were identified in the design and operating effectiveness of our internal control over financial reporting. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis.

Based on our assessment, we did not appropriately design and maintain entity-level controls impacting the control environment, risk assessment, control activities, information and communication and monitoring activities to prevent or detect material misstatements to the financial statements. These material weaknesses relate to:

(i) an insufficient number of qualified resources to ensure adequate oversight and accountability over the performance of controls, including:

- proper segregation of duties,
- controls over the completeness and accuracy of information used in the operation of control activities across substantially all financial statement areas, and
- retention of control evidence, and

(ii) improper access and a lack of review over user access and user provisioning as it relates to our information technology environment and general controls over information systems that support the financial reporting process.

These material weaknesses could result in a misstatement of our accounts or disclosures in our annual or interim financial statements that would not be prevented or detected on a timely basis.

These material weaknesses have not been remediated as of the date of this Annual Report on Form 10-K. To remediate the material weaknesses, we continue to hire finance and accounting personnel, as well as improve our financial controls and accounting systems. We continue using the services of a third-party firm to assist in the design and implementation of controls. We intend to continue to take further steps to remediate these material weaknesses through formalizing documentation of policies and procedures and further evolving the accounting processes. The material weaknesses will not be considered remediated until management completes the design and implementation of the measures described above and the controls operate for a sufficient period of time and management has concluded, through testing, that these controls are effective. Although we currently expect to remediate these material weaknesses by December 31, 2026, we cannot assure you that we will be able to successfully do so on this timeline.

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

If we fail to remediate our existing material weaknesses or identify new material weaknesses in our internal control over financial reporting, if we are unable to comply with the disclosure and attestation requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, if we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm is unable to conclude that our internal control over financial reporting is effective when we are no longer an emerging growth company, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock could be negatively affected. As a result, we could also become subject to investigations by Nasdaq, the SEC or other regulatory authorities, and become subject to litigation from investors and stockholders, which could harm our reputation and financial condition or divert financial and management resources from our regular business activities.

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

The precise incidence and prevalence for all the conditions we aim to address with our product candidate are unknown. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our product candidate, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including sales of our competitors, scientific literature,

surveys of clinics, patient foundations, or market research, and may prove to be incorrect in general, or as to their applicability to our company. Further, new trials may change the estimated incidence or prevalence of these diseases. The total addressable market of our product candidate, if approved, will ultimately depend upon, among other things, the diagnosis criteria included in the final label for our product candidate approved for sale for these indications, if any, the ability of our product candidate to improve on the safety, convenience, cost, and efficacy of competing therapies or therapies in development, acceptance by the medical community and patients, drug pricing, and reimbursement. The number of patients in the United States and other major markets and elsewhere may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our product, if approved, and our product candidate or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our business, financial condition, results of operations, and prospects.

Our business could be adversely affected by the effects of health pandemics or epidemics, which could cause significant disruptions in our operations and those of our current or future CDMOs, CROs, and other third parties upon whom we rely.

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

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

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

risks and uncertainties, including the burden of complying with complex and changing foreign regulatory, tax, accounting, and legal requirements, and reduced protection of intellectual property rights in some foreign countries.

Risks Related to Intellectual Property, Collaborations, and Related Agreements

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

We rely upon a combination of patents, know-how, trade secrets, and confidentiality agreements, to protect the intellectual property related to our technologies, and product candidate and to prevent third parties from copying and surpassing our achievements, thus eroding our competitive position in our market. We may also rely on protection afforded by in-licensed intellectual property rights and proprietary technology of third parties in the future.

Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries for our product candidate and its uses, as well as our ability to operate without infringing, misappropriating, or otherwise violating the proprietary rights of others. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our novel discoveries and technologies that are important to our business. Although we own issued patents, our pending and future patent applications may not result in patents being issued. Even if our patent applications result in issued patents, we cannot assure you that such issued patents will afford sufficient protection of our product candidate or its intended uses against competitors, nor can there be any assurance that the patents issued will not be infringed, designed around, invalidated by third parties, or that they will effectively prevent others from commercializing competitive technologies, products, or product candidates.

Obtaining and enforcing patents is expensive and time-consuming, and we may not be able to file, prosecute, maintain, enforce, or license all necessary or desirable patent applications or maintain and/or enforce patents that may issue based on our patent applications at a reasonable cost or in a timely manner. We may not be able to obtain or maintain patent applications and patents due to the subject matter claimed in such patent applications and patents being in disclosures in the public domain. It is also possible that we will fail to identify patentable aspects of our research and development results before it is too late to obtain patent protection. Therefore, patents and applications that are relevant to our product candidate may not be prosecuted and enforced in a manner consistent with the best interests of our business. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, CROs, CDMOs, consultants, advisors, and other third parties, any of these parties may breach these agreements and disclose such results before a patent application is filed, thereby jeopardizing our ability to seek patent protection. Consequently, we may not be able to prevent any third parties from using any of our technologies that are in the public domain to compete with our technologies or product candidate.

Composition of matter patents for pharmaceutical product candidates often provide a strong form of intellectual property protection for those types of products, as such patents provide protection without regard to any method of use or preparation. However, we cannot be certain that the claims in any of our patent applications directed to composition of matter of our product candidate will be considered patentable by the United States Patent and Trademark Office, or the 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. Further, our issued composition of matter patents covering our pharmaceutical product candidate may expire at such a date that our patents may not prevent competitors from developing, making and marketing a product that is identical to our product candidate after expiration of any applicable regulatory exclusivities. Similarly, patents for pharmaceutical formulations containing pharmaceutical product candidates may provide an additional form of intellectual property protection, as such patents provide protection without regard to any method of use. However, we cannot be certain that the claims in our pending patent applications directed to pharmaceutical formulations containing our product candidate will be considered patentable by the 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. In addition, we cannot be certain that the claims of such patents, if granted, will be sufficiently broad to effectively prevent competitors from working around our claimed inventions by developing alternative compounds and thereby competing with us without infringing our patent rights. Method of use patents protect the use of a product for the specified method or indication. In the absence of separate composition of

matter protection, this type of patent does not prevent a competitor from making and marketing a product that is identical to our product candidate for an indication that is outside of the methods of use claimed in our patents. Moreover, even if competitor products are not approved for use in our patented indications, and our competitors do not actively promote their products for indications that are covered by our patents, clinicians may prescribe these competitor products "off-label." Although off-label prescriptions may infringe or contribute to the infringement of method of use patents, such infringement is difficult to prevent or prosecute.

The patent position of pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has in recent years been the subject of much litigation, resulting in court decisions, including Supreme Court decisions, which have increased uncertainties as to the ability to enforce patent rights in the future. As a result, the issuance, scope, validity, enforceability, and commercial value of any patent rights are highly uncertain. Our pending and future owned and in-licensed patent applications may not result in patents being issued that protect our technologies or product candidate, effectively prevent others from commercializing our technologies or product candidate or otherwise provide any competitive advantage. In fact, patent applications may not issue as patents at all. The coverage claimed in a patent application can also be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States, or vice versa.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we will be successful in protecting our product candidate by obtaining and defending patents. For example, we may not be aware of all third-party intellectual property rights potentially relating to our product candidate or its intended uses, and as a result the impact of such third-party intellectual property rights upon the patentability of our patents and patent applications, as well as the impact of such third-party intellectual property upon our freedom to operate, is highly uncertain. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing or, in some cases, not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. If a third party can establish that we were not the first to make or the first to file for patent protection of such inventions, our patent applications may not issue as patents and even if issued, may be challenged and invalidated or rendered unenforceable. As a result, the issuance, inventorship, scope, validity, enforceability, and commercial value of our patent rights are highly uncertain.

The issuance of a patent is not conclusive as to its inventorship, scope, validity, or enforceability, and our pending patent applications may be challenged in patent offices in the United States and abroad. Even issued patents may later be found invalid or unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. For example, our pending patent applications may be subject to third-party pre-issuance submissions of prior art to the USPTO, and our issued patents may be subject to post-grant review, proceedings, oppositions, derivations, reexaminations, interferences, *inter partes* review proceedings, or other similar proceedings, in the United States or elsewhere, challenging our patent rights. Such submissions may also be made prior to a patent's issuance, precluding the granting of a patent based on one or more of our pending patent applications. An adverse determination in any such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated, or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technologies and product candidates, or limit the duration of the patent protection of our technologies and product candidate. Such challenges also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. Any of the foregoing could impair our competitive position and adversely affect our business, financial condition, results of operations, and prospects.

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

In addition, given the amount of time required for the development, testing, and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. The degree of future protection for our proprietary rights is uncertain. Only limited protection may be available and may

not adequately protect our rights or permit us to gain or keep any competitive advantage. Any failure to obtain or maintain patent protection with respect to our product candidate or its uses could adversely affect our business, financial condition, results of operations, and prospects.

Issued patents covering our product candidate, or the method of use of our product candidate could be found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad.

If we initiate legal proceedings against a third party to enforce a patent covering our product candidate, or our other proprietary technologies, the defendant could counterclaim that such patent is 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, insufficient written description, or failure to claim patent-eligible subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. In addition to such counterclaims, third parties may raise claims challenging the validity or enforceability of a patent before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post-grant review, *inter partes* review, derivation proceedings, and equivalent proceedings in foreign jurisdictions (*e.g.*, opposition proceedings). Such proceedings could result in the revocation of, cancellation of, or amendment to our patent rights in such a way that they no longer cover our product candidate, therapeutic programs, and other proprietary technologies we may develop. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art of which we and the patent examiner were unaware during prosecution. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection provided to our product candidate, proprietary technologies, or other components of our therapeutic programs, as applicable. Such a loss of patent protection could have a material adverse impact on our business, financial condition, results of operations, and prospects.

We may not be successful in obtaining or maintaining necessary rights to third party patents for our product candidate through acquisitions and in-licenses.

The growth of our business may depend in part on our ability to acquire, in-license, or use third-party intellectual property and proprietary rights. Other pharmaceutical companies and academic institutions may own patents or may have filed, or be planning to file, patent applications potentially relevant to our business. In order to avoid infringing such patent rights, we may find it necessary or prudent to obtain licenses to such patent rights from such third parties. For example, we may be required by the FDA or comparable foreign regulatory authorities to provide a specific companion diagnostic test or tests with our product candidate, any of which could require us to obtain rights to use patents or know-how owned or controlled by third parties. In addition, with respect to any patent or other intellectual property rights we may co-own with third parties in the future, we may require licenses to such co-owners' interest to such patent or other intellectual property rights. We may be unable to acquire or in-license any compositions, methods of use, processes, or other third-party intellectual property rights from third parties that we identify as necessary or important to our business operations. In addition, we may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. Were that to happen, we may need to cease use of the compositions or methods covered by those third-party intellectual property rights and may need to seek to develop alternative approaches that do not infringe, misappropriate, or otherwise violate those 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, it may be non-exclusive, which means that our competitors may also receive access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology.

The licensing and acquisition of third-party intellectual property rights is a competitive area, 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 candidate. More established companies may have a competitive advantage over us due to their size, resources, and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. There can be no assurance that we will be able to successfully complete these types of negotiations and ultimately acquire the rights to the intellectual property related to the products or product candidate that we may seek to develop or market. 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 certain programs and our business, financial condition, results of operations, and prospects could suffer.

We may enter into license agreements in the future with others to advance our existing or future research or allow commercialization of our existing or future product candidates. These licenses may not provide exclusive rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technologies and product candidate in the future. In that event, we may be required to expend significant time and resources to redesign our product candidate, or the methods for manufacturing them, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected product candidate, which could harm our business, financial condition, results of operations, and prospects significantly. We cannot provide any assurances that third-party patents do not exist which might be enforced against our current manufacturing methods, product candidate, or future methods or product candidates resulting in either an injunction prohibiting our manufacture or future sales, or, with respect to our future sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties, which could be significant.

We may form or seek collaborations or strategic alliances, enter into licensing arrangements or other business transactions in the future, and we may not realize the benefits of such transactions.

We may enter into licensing arrangements and strategic transactions to acquire and advance new assets or product candidates in the future, including strategic partnerships, in-licensing of product candidates, strategic collaborations, joint ventures, restructurings, divestitures, acquisitions of companies, asset purchases, business combinations, and investments.

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

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

In addition, any future transactions could increase our near and long-term expenditures, result in potentially dilutive issuances of our equity securities, including our common stock, or the incurrence of debt, contingent liabilities,

amortization expenses, or acquired in-process research and development expenses, any of which could affect our financial condition, liquidity, and results of operations.

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

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

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

Moreover, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws. Additionally, laws of some countries outside of the United States and Europe do not afford intellectual property protection to the same extent as the laws of the United States and Europe. Various companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of many countries do not favor the enforcement of patents or other intellectual property protection, particularly those relating to pharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights.

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

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

In addition, geopolitical actions in the United States and in foreign countries could increase the uncertainties and costs surrounding the prosecution or maintenance of our patent applications or those of any future licensors and the maintenance, enforcement, or defense of our issued patents or those of any future licensors. As a result, our competitive position may be impaired, and our business, financial condition, results of operations, and prospects may be adversely affected.

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

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

- others may be able to make or use product candidates that are similar to ours, but that are not covered by the claims of our patents or pending patent applications;
- we or future collaborators might not have been the first to make the inventions covered by the pending patent application that we own or have exclusively licensed;
- we or future collaborators might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing or otherwise violating our intellectual property rights;
- it is possible that noncompliance with the USPTO and foreign governmental patent agencies' requirements for a number of procedural, documentary, fee payment, and other provisions during the patent process can result in abandonment or lapse of a patent or patent application, and partial or complete loss of patent rights in the relevant jurisdiction;
- it is possible that our pending patent applications or those that we may own or license in the future will not lead to issued patents;
- issued patents, if any arise in the future, that we either own or have exclusively licensed may be revoked, modified, or held invalid or unenforceable, as a result of legal challenges by our competitors or other third parties;
- others may have access to the same intellectual property rights licensed to us in the future on a non-exclusive basis;
- our competitors or other third parties might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- we cannot predict the scope of protection of any patent issuing based on our patent applications, including whether the patent applications that we own, or, in the future, in-license will result in issued patents with claims that directed to our product candidate or uses thereof in the United States or in other foreign countries;
- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns;
- countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop, and market competing product candidates;
- the claims of any patent issuing based on our patent applications may not provide protection against competitors or any competitive advantages, or may be challenged by third parties;
- if enforced, a court may not hold that our patents, if they issue in the future, are valid, enforceable, and infringed;
- we may need to initiate litigation or administrative proceedings to enforce and/or defend our patent rights which will be costly whether we win or lose;
- we may choose not to file a patent application in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent application covering such intellectual property;
- our trade secrets or proprietary know-how may be unlawfully disclosed, thereby losing their trade secret or proprietary status;

- we may fail to adequately protect and police our trademarks and trade secrets; and
- the patents of others may have an adverse effect on our business, including if others obtain patents claiming subject matter similar to or improving that covered by our patent applications.

Even if we receive regulatory approval for our product candidate, the regulatory authorities may also approve generic products that compete directly with our product candidate. Once an NDA is approved, the product covered thereby becomes a "listed drug" which can, in turn, be cited by potential competitors in support of approval of an Abbreviated New Drug Application, or ANDA. The FDA regulations and other applicable regulations and policies provide incentives to manufacturers to create non-infringing versions of a listed drug to facilitate the approval of an ANDA for generic substitutes. These manufacturers might only be required to conduct a relatively inexpensive study to show that their product has the same active ingredient(s), dosage form, strength, route of administration and conditions of use or labeling as our product candidate and that the generic product is bioequivalent to our product candidate. These generic equivalents could be significantly less costly than ours to bring to market and companies that produce generic equivalents may be able to offer their products at lower prices. Accordingly, competition from generic equivalents of our product candidate could materially adversely impact our ability to successfully commercialize our product candidate.

Should any of these or similar events occur, they could significantly harm our business, financial condition, results of operations, and prospects.

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

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

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

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

incorrect. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our product candidate.

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

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

Competitors or other third parties may infringe, misappropriate, or violate our patents, trademarks, or other intellectual property. To counter infringement, misappropriation, or unauthorized use, we or one of our licensing partners may be required to file infringement claims, which can be expensive and time-consuming and divert the time and attention of our management and scientific personnel. Our pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents, in addition to counterclaims asserting that our patents are invalid or unenforceable, or both. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement, insufficient written description, or failure to claim patent-eligible subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. The outcome following legal assertions of invalidity and unenforceability is unpredictable. In any patent infringement proceeding, there is a risk that a court will decide that a patent of ours 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 patent 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 other party's use of our 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). An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitors and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Any of these occurrences could adversely affect our competitive position, and our business, financial condition, results of operations, and prospects. Similarly, if we assert trademark infringement claims, a court may determine that the marks to be asserted are invalid or unenforceable, or that the party against whom trademark infringement to be asserted has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

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

Intellectual property rights of third parties could adversely affect our ability to commercialize our product candidate or any future product candidates, and we, or any future licensors, collaborators or strategic partners may become subject to third party claims or litigation alleging infringement of patents or misappropriation or violation of our other proprietary rights or seeking to invalidate patents or other proprietary rights. We might be required to litigate or

obtain licenses from third parties in order to develop or market our product candidate or any future product candidates. Such litigation or licenses could be costly or not available on commercially reasonable terms.

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

There is a substantial amount of intellectual property litigation in the pharmaceutical industry, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to our product candidate. We cannot be certain that our product candidate will not infringe existing or future patents owned by third parties. Third parties may assert infringement claims against us based on existing or future intellectual property rights, regardless of their merit. We may decide in the future to seek a license to such third-party patents or other intellectual property rights, but we might not be able to do so on reasonable terms. Proving patent invalidity may be difficult. For example, in the United States, proving invalidity in court requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. As this burden is a high one, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such United States patent or find that our technologies or product candidate does not infringe any such claims. If we are found to infringe, misappropriate, or otherwise violate a third party's intellectual property rights, we could be forced, including by court order, to cease developing, manufacturing, or commercializing the infringing technology or product candidate. Further, we may be required to redesign the technology or product candidate in a non-infringing manner, which may not be commercially feasible. Alternatively, we may be required to obtain a license from such third party in order to use the infringing technology and continue developing, manufacturing, or marketing the infringing product candidate. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our technologies or product candidate or force us to cease some of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

We may not be aware of patents that have already been issued and that a third party, for example, a competitor in the fields in which we are developing our product candidate, might assert are infringed by our current or future product candidates, including claims to compositions, formulations, methods of manufacture, or methods of use or treatment that cover our current or future 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 current or future product candidates, could be found to be infringed by our current or future product candidates. In addition, because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our current or future product candidates may infringe. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit, or otherwise interfere with our ability to make, use, and sell our current or future product candidates. The pharmaceutical industry has produced a considerable number of patents, and it may not always be clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we were sued for patent infringement, we would need to demonstrate that our current or future product candidates or methods of use either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be able to do this. Proving

invalidity may be difficult. For example, in the United States, proving invalidity in court requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents, and there is no assurance that a court of competent jurisdiction would invalidate the claims of any such United States patent. Even if we are successful in these proceedings, we may incur substantial costs, and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could adversely affect our business and operations. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. In addition, we may not have sufficient resources to bring these actions to a successful conclusion.

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

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

As is the case with other pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining, defending, maintaining, and enforcing patents in the pharmaceutical industry involves both technological and legal complexity and is therefore costly, time-consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents, and may diminish our ability to protect our inventions, obtain, maintain, enforce and protect our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our future owned and licensed patents. For example, patent reform legislation in the United States and other countries, such as the Leahy-Smith America Invents Act, or the Leahy-Smith Act, signed into law on September 16, 2011, could increase those uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our future issued patents. The Leahy-Smith Act included a number of significant changes to United States patent law. These changes included provisions that affected the way patent applications are prosecuted, redefined prior art, and provided more efficient and cost-effective avenues for competitors to challenge the validity of patents. These included allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, *inter partes* review, and derivation proceedings.

Further, because of a lower evidentiary standard in these USPTO post-grant proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to find a claim not patentable even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to successfully attack our patent claims with evidence that would not have been sufficient to invalidate those claims if first challenged by a defendant in a district court action. Thus, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our future issued patents, all of which could adversely affect our business, financial condition, results of operations, and prospects.

After March 2013, under the Leahy-Smith Act, the United States transitioned to a first inventor to file system in which, assuming that the other statutory requirements are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third-party was the first to invent the claimed invention. Consequently, if a third party that files a patent application in the USPTO before we file an application covering the same invention, the third party could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we were the first to either (i) file any patent application related to our product candidate and other proprietary technologies we may develop or (ii) invent any of the inventions claimed in our patents or patent applications. Even where we have a valid and enforceable patent, we may not be able to

exclude others from practicing the claimed invention where the other party can show that they used the invention in commerce before our filing date or the other party benefits from a compulsory license. Thus, the changes to the United States patent system by the Leahy-Smith Act introduces uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents, all of which could adversely affect our business, financial condition, results of operations, and prospects.

In addition, the patent positions of companies in the development and commercialization of pharmaceuticals are particularly uncertain. The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. Depending on future actions by the United States Congress, the United States courts, the USPTO, and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents and patents that we might obtain in the future. For example, recent decisions raise questions regarding the award of patent term adjustment, or PTA, for patents where related patents have issued without PTA. Thus, it cannot be said with certainty how PTA will or will not be viewed in future and whether patent expiration dates may be impacted.

Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in 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 may obtain in the future. For example, the complexity and uncertainty of European patent laws have also increased in recent years. In Europe, a new unitary patent system took effect on June 1, 2023, which will significantly impact European patents, including those granted before the introduction of such a system. Under the unitary patent system, all European patents, including those issued prior to June 1, 2023, now by default automatically fall under the jurisdiction of a new European Unified Patent Court, or the UPC, for litigation involving such patents. As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation. Our European patent applications, if issued, could be challenged in the UPC. During the first seven years of the UPC's existence, the UPC legislation allows a patent owner to opt its European patents out of the jurisdiction of the UPC. We may decide to opt out our future European patents from the UPC, but doing so may preclude us from realizing the benefits of the UPC. Moreover, if we do not meet all of the formalities and requirements for opt-out under the UPC, our future European patents could remain under the jurisdiction of the UPC. The UPC will provide our competitors with a new forum to centrally revoke our European patents, and allow for the possibility of a competitor to obtain pan-European injunction. It is uncertain how the UPC will impact granted European patents in the pharmaceutical industry. We cannot predict how future decisions by the courts, the United States Congress, or the USPTO may impact the value of our patents. Any similar adverse change in the patent laws of other jurisdictions could also adversely affect our business, financial condition, results of operations, and prospects.

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

We may be subject to claims that former employees, collaborators, or other third parties have an interest in our 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 candidate, or as a result of questions regarding co-ownership of potential joint inventions. Litigation may be necessary to resolve these and other claims challenging inventorship or ownership. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could adversely affect our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

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

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

Patent terms may be inadequate to protect our competitive position on our product candidate for a sufficient amount of time.

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

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

Depending upon the timing, duration, and specifics of any FDA marketing approval of our product candidate, one or more of our issued United States patents or issued United States patents that we may own in the future may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Action of 1984, or the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent extension term of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. Similar patent term restoration provisions to compensate for commercialization delay caused by regulatory review are also available in certain foreign jurisdictions, such as the EU Regulation (EC) No 469/2009 concerning the Supplementary Protection Certificate for medicinal products. However, we may not be granted any extensions for which we apply because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. In addition, to the extent we wish to pursue patent term extension based on a patent that we in-license from a third party, we would need the cooperation of that third party. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension, or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations, and prospects could be materially harmed.

Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated as a result of noncompliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees, and various other government fees on patents and/or applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our patents and patent applications. We rely on our outside counsel or third party vendors to pay these fees due to United States and non-United States patent agencies. The USPTO and various non-United States government patent agencies require compliance with several procedural, documentary, fee payment, and other similar provisions during the patent application process. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market and this circumstance could adversely affect our business, financial condition, results of operations, and prospects.

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

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce, and any other elements of our discovery and development processes that involve proprietary know-how, information, or technology that is not covered by patents. We may also rely on trade secret protection as temporary protection for concepts that may be included in a future patent filing. However, trade secret protection will not protect us from innovations that a competitor develops independently of our proprietary know-how. If a competitor independently develops a technology that we protect as a trade secret and files a patent application on that technology, then we may not be able to patent that technology in the future, may require a license from the competitor to use our own know-how, and if the license is not available on commercially viable terms, then we may not be able to launch our product candidate. Additionally, trade secrets can be difficult to protect and some courts inside and outside the United States are less willing or unwilling to protect trade secrets. The laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws within the United States. We may need to share our trade secrets and proprietary know-how with current or future partners, collaborators, contractors, and others located in countries at heightened risk of theft of trade secrets, including through direct intrusion by private parties or foreign actors, and those affiliated with or controlled by state actors. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. Additionally, although we require all of our employees to assign their inventions to us, and require all of our employees, consultants, advisors, and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets. If our trade secrets are not adequately protected, our business, financial condition, results of operations, and prospects could be adversely affected.

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

Our trademarks or trade names may be challenged, infringed, circumvented, or declared generic or determined to be infringing on other marks. During trademark registration proceedings, we may receive rejections of our applications by the USPTO or in other foreign jurisdictions. Although we are given an opportunity to respond to such rejections, we may be unable to overcome them. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, which may not survive such proceedings. Moreover, any name we propose to use with our product candidate in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. Similar requirements exist in Europe. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA or an equivalent administrative body in a foreign jurisdiction objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties, and be acceptable to the FDA. Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark.

We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade names, domain name, or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our business, financial condition, results of operations, and prospects.

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

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

In addition, we may in the future be subject to claims by former employees, consultants, or other third parties asserting an ownership right in our patents or patent applications. An adverse determination in any such submission or proceeding may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated, or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar technology and therapeutics, without payment to us, or could limit the duration of the patent protection covering our technologies and product candidate. Such challenges may also result in our inability to develop, manufacture, or commercialize our technologies and product candidate 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 technologies and product candidates. Any of the foregoing could adversely affect our business, financial condition, results of operations, and prospects.

We may develop or license intellectual property for which development was funded or otherwise assisted by, the U.S. government and/or government agencies, such as the National Institutes of Health, for development of our technology and product candidates. Failure to meet our own obligations to future licensors or upstream licensors, including such government agencies, may result in the loss of our rights to such intellectual property, which could harm our business.

The U.S. government and/or government agencies in the future may provide, funding, facilities, personnel or other assistance in connection with the development of the intellectual property rights owned by or licensed to us. The U.S. government and/or government agencies may retain 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. For example, research resulting in future in-licensed patent rights and technology that was funded in part by the U.S. government could result in the government having certain rights, or march-in rights, to such patent rights and technology which may permit the government to disclose our confidential information to third parties and to exercise march-in rights to use or allow third parties to use our licensed technology.

Risks Related to Our Reliance on Third Parties

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

We rely on our internal, proprietary systems for data collection and our own clinical trial team to conduct our clinical trials in addition to external vendors and CROs to comprise a full clinical trial team. If our clinical trial team does not

comply with applicable regulatory requirements, meet expected deadlines, or run trials effectively, our development programs and our ability to seek or obtain regulatory approval for or commercialize our product candidate may be delayed. Because we currently rely and intend to continue to rely on these third parties, we will have less control over the timing, quality, and other aspects of clinical trials than we would have had we conducted them independently. These parties are not, and will not be, our employees and we will have limited control over the amount of time and resources that they dedicate to our programs. Additionally, such parties may have contractual relationships with other entities, some of which may be our competitors, which may draw time and resources from our programs and harm our competitive position. As a result, delays may occur, which could negatively impact our ability to meet our expected clinical development timelines and harm our business, financial condition, and prospects.

We also rely on other third parties to store and distribute drug supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or regulatory approval of our product candidate or commercialization of any resulting products, producing additional losses and depriving us of potential product revenue.

Our reliance on these third parties for development activities will reduce our control over these activities. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable trial protocol and applicable legal, regulatory, and scientific standards, and our reliance on clinical trial sites and other third parties does not relieve us of these responsibilities. For example, we will remain responsible for ensuring that each of our preclinical studies is conducted in accordance with good laboratory practices, or GLPs, and clinical trials are conducted in accordance with GCPs. Moreover, the FDA and comparable foreign regulatory authorities require us to comply with GCPs for conducting, recording, and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity, and confidentiality of trial participants are protected. Regulatory authorities enforce these requirements through periodic inspections (including pre-approval inspections once an NDA is submitted to the FDA) of trial sponsors, clinical investigators, clinical trial sites, and IRBs. If we, our clinical trial sites, or other third parties fail to comply with applicable GLP, GCP, or other regulatory requirements, we or they may be subject to enforcement or other legal actions, the clinical data generated in our clinical trials may be deemed unreliable, and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications, if ever. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCPs. Moreover, our business may be significantly impacted if our clinical investigators or other third parties violate federal or state healthcare fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

In addition, principal investigators for our clinical trials may be asked to serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or the FDA concludes that the financial relationship may have affected the interpretation of the study, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection by the FDA of any NDA we submit. Any such delay or rejection could prevent us from commercializing our product candidate.

Further, if our third party contractors do not successfully carry out their contractual duties, meet expected deadlines, or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, our clinical trials may need to be repeated, extended, delayed, or terminated and we may not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidate, and we may not be able to, or may be delayed in our efforts to, successfully commercialize our product candidate(s) or we or they may be subject to regulatory enforcement actions. As a result, our results of operations and the commercial prospects for our product candidate would be harmed, our costs could increase and our ability to generate revenue could be delayed. To the extent we are unable to successfully identify and manage the performance of third-party service providers in the future, our business may be materially and adversely affected.

If any of our relationships with these third parties terminate, we may not be able to enter into alternative arrangements or do so on commercially reasonable terms. Switching or adding additional contractors involves additional cost and time and requires management's time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, delays could occur, which could compromise our ability to meet our desired development timelines. Though we work to carefully manage our relationships with our third-party investigators and other third parties, 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 material adverse impact on our business, financial condition, and prospects. In addition, if an

agreement with any of our collaborators terminates, our access to technology and intellectual property licensed to us by that collaborator may be restricted or terminate entirely, which may delay our continued development of our product candidate utilizing the collaborator's technology or intellectual property or require us to stop development of such product candidate completely.

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

We do not own or operate facilities for drug manufacturing, storage, distribution, or quality testing and have no current plans to develop our own clinical or commercial-scale manufacturing capabilities. We currently rely, and expect to continue to rely, on third-party contract developers and manufacturers to manufacture bulk drug substances, drug products, raw materials, and other components for our product candidate and delivery devices, as well as for commercial manufacture if our product candidate receives regulatory approval. Reliance on third-party manufacturers may expose us to different risks than if we were to manufacture the product candidate ourselves. There can be no assurance that our clinical development product supplies will not be limited, interrupted, terminated, or will be of satisfactory quality or be available at acceptable prices. In addition, any replacement of our manufacturer could require significant effort and time because there may be a limited number of qualified replacements.

The manufacturing process for our product candidate is subject to the FDA's review and, in the future, may be subject to comparable foreign regulatory authority review. We, our suppliers and our manufacturers must meet applicable manufacturing requirements and undergo rigorous facility and process validation tests required by regulatory authorities in order to comply with regulatory standards, such as cGMPs, and to ensure the quality and safety of drug products. Securing marketing approval also requires the submission of detailed information about the product manufacturing process to, and inspection of manufacturing facilities by, the FDA and, in the future, comparable foreign regulatory authorities. If our CDMOs cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or comparable foreign regulatory authorities, they will not be able to secure and/or maintain regulatory approval for the use of their manufacturing facilities to produce our product candidate. Moreover, we do not conduct the manufacturing process ourselves and are completely dependent on our CDMOs for manufacturing our product candidate in compliance with cGMP and other applicable requirements. In the event that any of our manufacturers fails to comply with such requirements or to perform its obligations in relation to quality, timing, or otherwise, or if our projected manufacturing capacity or supply of materials becomes limited, interrupted, or more costly than anticipated, we may be forced to enter into an agreement with another third party, which we may not be able to do timely or on reasonable terms, if at all.

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

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

- an inability to initiate or complete clinical trials of product candidate in a timely manner;

- delay in submitting regulatory applications, or receiving regulatory approvals, for product candidate;
- subjecting third-party manufacturing facilities to additional inspections by regulatory authorities;
- loss of the cooperation of existing or future collaborators;
- requirements to cease development or to recall batches of our product candidate; and
- in the event of approval to market and commercialize a product candidate, an inability to meet commercial demands for our products.

Reliance on third-party manufacturers entails additional risks such as limitations on supply availability resulting from capacity and scheduling constraints of third parties; the possible breach of manufacturing agreements by third parties because of factors beyond our control; the possible termination or non-renewal of the manufacturing agreements by the third party, at a time that is costly or inconvenient to us; failure to manufacture our product according to our schedule or at all; and the possible misappropriation of our proprietary information, including our trade secrets and know-how. Additionally, our CDMOs may experience difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If any of our CDMOs were to encounter any of these difficulties, our ability to provide our product candidate to participants in clinical trials, or to provide product for treatment of patients if approved, would be jeopardized. Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval, and any related remedial measures may be costly or time-consuming to implement, which would have a material adverse impact on our financial position.

If any third-party manufacturer of our product candidate is unable to increase the scale of its production of our product candidate, and/or increase the product yield of its manufacturing, then our costs to manufacture product candidate may increase and commercialization may be delayed.

In order to produce sufficient quantities to meet the demand for clinical trials and, if approved, subsequent commercialization of our products, our third-party manufacturers will be required to increase their production and optimize their manufacturing processes while maintaining the quality of the output. The transition to larger scale production could prove difficult. In addition, if our third-party manufacturers are not able to optimize their manufacturing processes to increase the product yield for our product candidate, or if they are unable to produce increased amounts of our product candidate while maintaining the quality of the product, then we may not be able to meet the demands of clinical trials or market demands, which could decrease our ability to generate profits and have a material adverse impact on our business and results of operation.

We depend on limited source suppliers for certain drug substances, drug products, raw materials, components, and other materials used in our product candidate. If we are unable to source these supplies on a timely basis, we will not be able to complete our clinical trials on time and the development of our product candidate may be delayed.

We depend on limited source suppliers for certain drug substances, drug products, raw materials, samples, components, and other materials used in our product candidate. Currently, there are limited sources of raw materials and starting materials used in the manufacture of LB-102, and we rely on a single CDMO for the manufacture of LB-102 drug substance. Any change in our relationships with our CDMOs or changes to contractual terms of our agreements with them could adversely affect our business, financial condition, results of operations, and prospects.

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

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

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

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

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

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

We may have conflicts with our current or future collaborators, such as conflicts concerning the interpretation of preclinical or clinical data, the achievement of milestones, the interpretation of contractual obligations, payments for services, development obligations, or the ownership of intellectual property developed during our collaboration. Moreover, a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to the marketing and distribution of such product or products. If any conflicts arise with any of our collaborators, such collaborator may act in a manner that is adverse to our best interests. Any such disagreement could result in one or more of the following, each of which could delay or prevent the development or commercialization of our product candidate, and in turn prevent us from generating revenue: disputes regarding milestone payments or royalties; uncertainty regarding ownership of intellectual property rights arising from our collaborative activities, which could prevent us from entering into additional collaborations; unwillingness by the collaborator to cooperate in the development or manufacture of a product candidate, including providing us with data or materials; unwillingness on the part of a collaborator to keep us informed regarding the progress of its development and commercialization activities or to permit public disclosure of the results of those activities; initiating of litigation or alternative dispute resolution options by either party to resolve the dispute; or attempts by either party to terminate the agreement. Collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates.

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.

Because we currently rely on third parties to manufacture our product candidate and to perform quality testing, we must, at times, share our proprietary technology and confidential information, including trade secrets, with them. We seek to protect our proprietary technology, in part, by entering into confidentiality agreements, and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements, or other similar agreements with our collaborators, advisors, employees, 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. 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 intentionally or 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 and despite our efforts to protect our trade secrets, a competitor's discovery of our proprietary technology and confidential information or other unauthorized use or disclosure would impair our competitive position and may have a material adverse effect on our business, financial condition, results of operations, and prospects.

We may engage third party collaborators to market and commercialize our product candidate, who may fail to effectively commercialize our product candidate.

We may utilize strategic partners or contract sales forces, where appropriate, to assist in the commercialization of our product candidate, if approved. We currently possess limited resources and may not be successful in establishing collaborations or co-promotion arrangements on acceptable terms, if at all. We also face competition in our search for collaborators and co-promoters. By entering into strategic collaborations or similar arrangements, we will rely on third parties for financial resources and for development, commercialization, sales and marketing and regulatory expertise. Any collaborators may fail to develop or effectively commercialize our product candidate because they cannot obtain the necessary regulatory approvals, they lack adequate financial or other resources or they decide to focus on other initiatives. Any failure to enter into collaboration or co-promotion arrangements or the failure of our third party collaborators to successfully market and commercialize our product candidate would diminish our revenues and harm our results of operations. In addition, conflicts may arise with our collaborators, such as conflicts concerning the interpretation of clinical data, the achievement of milestones, the interpretation of financial provisions or the ownership of intellectual property. If any conflicts arise with our collaborators, they may act in their self-interest, which may be adverse to our best interest.

Risks Related to Government Regulation

Our relationships with healthcare providers, including physicians, and third-party payors may be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to significant penalties, including criminal sanctions, civil penalties, contractual damages, reputational harm, and diminished profits and future earnings.

Healthcare providers, including physicians, and third-party payors in the United States and elsewhere play a primary role in the recommendation and prescription of pharmaceutical products. Our current and future arrangements with healthcare providers, third-party payors, and customers can expose us to broadly applicable fraud and abuse and other healthcare laws and regulations, which may constrain the business or financial arrangements and relationships through which we research, and if approved, sell, market, and distribute our products. In particular, the research of our product candidate, as well as the promotion, sales, and marketing of a future approved product, is subject to extensive laws designed to prevent fraud, kickbacks, self-dealing, and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring, and commission(s), certain customer incentive programs, and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials. The applicable federal, state, and foreign healthcare laws and regulations laws that may affect our ability to operate now or in the future include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering, or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order, or recommendation of any good, facility, item, or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity can be found guilty of violating the statute without actual knowledge of the statute or specific intent to violate it. The federal 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. The civil monetary penalties statute which imposes penalties against any person or entity who, among other things, is determined to have presented or caused to be presented a claim to, among others, a federal healthcare program that the person knows or should know is for a medical or other item or service that was not provided as claimed or is false or fraudulent;

- the federal civil and criminal false claims laws, including the federal False Claims Act, or FCA, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false or fraudulent claims for payment to, or approval by Medicare, Medicaid, or other federal healthcare programs, knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim or an obligation to pay or transmit money to the federal government, or knowingly and improperly avoiding or decreasing or concealing an obligation to pay money to the federal government. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government healthcare programs if they are deemed to "cause" the submission of false or fraudulent claims. In addition, 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 FCA. The FCA also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (*e.g.*, public or private), and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact, or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items, or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity can be found guilty of violating the health care fraud statute under HIPAA without actual knowledge of the statute or specific intent to violate it;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, which also imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy and security of individually identifiable health information of covered entities subject to the rule, including health plans, healthcare clearinghouses and certain healthcare providers and their business associates, independent contractors of a covered entity that perform certain services involving the use or disclosure of individually identifiable health information for or on their behalf, as well as their covered subcontractors;

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

- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, and may be broader in scope than their federal equivalents; state and local laws that require certain regulatory licenses to manufacture or distribute our products commercially and/or the registration of pharmaceutical sales representatives in the jurisdiction; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and local laws that require the registration of pharmaceutical sales representatives.

The manufacturing and distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage, and security requirements intended to prevent the unauthorized sale of pharmaceutical products. Distribution of prescription drug samples to licensed prescribers is also highly regulated within the United States.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform. Federal, state, and foreign enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions, significant fines and penalties, and settlements in the healthcare industry. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and may divert our management's attention from the operation of our business.

It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations, or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal, and administrative penalties, damages, fines, disgorgement, individual imprisonment, possible exclusion from participation in federal and state funded healthcare programs, contractual damages, and the curtailment or restricting of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. Any action for violation of these laws, even if successfully defended, could cause us to incur significant legal expenses and divert management's attention from the operation of our business. Prohibitions or restrictions on sales or withdrawal of future marketed products could adversely affect our business, results of operations, and financial condition.

EU drug marketing and reimbursement regulations may materially affect our ability to market and receive coverage for our products in the EU member states.

We intend to seek approval to market our product candidate in the United States and we may also seek to do so in selected foreign jurisdictions, including the European Union. If we obtain approval in one or more foreign jurisdictions for our product candidate, we will be subject to rules and regulations in those jurisdictions. In some foreign countries, particularly those in the European Union, the pricing of medicinal products is subject to governmental control and other market regulations which could put pressure on the pricing and usage of our product candidate. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a product candidate. Some countries provide that products may be marketed only after a reimbursement decision has been taken by the relevant regulatory authority. In addition, market acceptance and sales of our product candidate will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for our product candidate and may be affected by existing and future health care reform measures.

Much like the federal Anti-Kickback Statute prohibition in the United States, the provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order, or use of medicinal products is also prohibited in the European Union. The provision of benefits or advantages to physicians is governed by the national anti-bribery laws of EU member states and the industry codes of conduct. Infringement of these laws or codes of conduct could result in substantial fines and imprisonment.

Payments made to healthcare professionals, healthcare organizations, students, or patient organizations in EU member states must increasingly be publicly disclosed. Moreover, agreements with healthcare professionals must be the subject of a prior written agreement between the parties and often must be the subject of prior notification and/or approval by the healthcare professional's employer, his or her competent professional organization, and/or the regulatory authorities of the individual EU member states. These requirements are provided in the national laws, industry codes, or professional codes of conduct applicable in the EU member states. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, or fines.

In addition, in most foreign countries, including the EU member states, the requirements governing drug pricing and reimbursement vary widely from country to country. For example, EU member states may restrict the range of medicinal products for which their national health insurance systems provide reimbursement and control the prices of medicinal products for human use. Reference pricing used by various EU member states and parallel distribution, or arbitrage between low-priced and high-priced EU member states, can further reduce prices. An EU member state may approve a

specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. In some countries, we may be required to conduct a clinical study or other studies that compare the cost-effectiveness of our product candidate to other available therapies in order to obtain or maintain reimbursement or pricing approval. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for our product. Historically, products launched in the European Union do not follow price structures of the United States and generally prices tend to be significantly lower. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If pricing is set at unsatisfactory levels or if reimbursement of our products is unavailable or limited in scope or amount, our revenues from sales by us or our strategic partners and the potential profitability of our product candidate in those countries would be negatively affected.

In December 2021, Regulation No. 2021/2282 on Health Technology Assessment, or HTA, amending Directive 2011/24/EU, was adopted. This regulation, which will apply from January 12, 2025 is intended to boost cooperation among EU member states in assessing health technologies, including new medicinal products, and providing the basis for cooperation at the EU level for joint clinical assessments in these areas. The regulation foresees a three-year transitional period individual EU member states will continue to be responsible for assessing non-clinical (*e.g.*, economic, social, ethical) aspects of health technologies, and making decisions on pricing and reimbursement. Entry into application of the HTA regulation is anticipated to increase reliance by competent national authorities on reference pricing mechanisms, the mechanism whereby countries reflect the reimbursement price in other EU member states. This has the potential to result in a decrease in reimbursement price in a number of EU member states to reflect the price fixed in the EU member state with the lowest reimbursement price.

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

If our product candidate is approved, it will be subject to extensive and ongoing regulatory requirements for manufacturing, labeling, packaging, distribution, storage, advertising, promotion, import, export, sampling, record-keeping, conduct of post-marketing studies and submission of safety, efficacy, and other post-market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities. In addition, we will be subject to continued compliance with cGMPs and similar requirements outside the United States and GCP requirements for any clinical trials that we conduct post-approval.

Manufacturers and manufacturers' facilities are required to comply with extensive FDA and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMPs or similar regulations. As such, we and our contract manufacturers will be subject to continual review and periodic, unannounced inspections by the FDA and other regulatory authorities to assess compliance with cGMPs or similar requirements and adherence to commitments made in any NDA, other marketing application, and previous responses to inspection observations. Accordingly, we and others with which we work must continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production, and quality control.

Any regulatory approvals that we may receive for our product candidate will require the submission of reports to regulatory authorities and surveillance to monitor the safety and efficacy of the product candidate, and such approvals may be subject to significant limitations on the approved indicated uses for which the product may be marketed (e.g., use restrictions for specified age groups, warnings, precautions or contraindications), and may include burdensome post-approval study or risk management requirements. For example, the FDA may require a REMS program as a condition of approval of our product candidate or similar risk management measures, which could entail requirements for long-term patient follow-up, a medication guide, physician training and communication plans, or additional elements to ensure safe use, such as restricted distribution methods, patient registries, and other risk minimization tools.

The FDA or comparable foreign regulatory authorities may impose consent decrees or 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 our product candidate, such as adverse events of unanticipated severity or frequency, or problems with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in restrictions on that product, the manufacturing facility or us, including

revisions to the approved labeling to add new safety information, contraindications or a "black box" warning, imposition of post-market studies or clinical trials to assess new safety risks, or imposition of distribution restrictions or other restrictions under a REMS. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of our products, withdrawal of the product from the market, or product recalls;
- fines, restitutions, disgorgement of profits or revenues, warning letters, untitled letters, or holds on clinical trials;
- refusal by the FDA or comparable foreign regulatory authorities to approve pending applications or supplements to approved applications submitted by us or suspension or revocation of approvals;
- product seizure or detention or refusal to permit the import or export of our products; and
- injunctions or the imposition of civil or criminal penalties.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidate and generate revenue and could require us to expend significant time and resources in response and could generate negative publicity.

The policies of the FDA and comparable regulatory authorities may change and additional government regulations may be enacted that could prevent, limit, or delay regulatory approval of our product candidate. 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 be subject to enforcement action and our business, results of operations, and financial condition could be adversely affected.

The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses.

The FDA and comparable foreign regulatory authorities strictly regulate marketing, labeling, advertising, and promotion of prescription drugs. These regulations include standards for direct-to-consumer advertising (in the United States only), industry-sponsored scientific and educational activities, and promotional activities involving the internet, as well as restrictions on promoting approved drugs for unapproved uses or patient populations (known as "off-label promotion"). Products may be promoted only for the approved indications and in accordance with the provisions of the approved label. While physicians in the United States may choose, and are generally permitted, to prescribe drugs for off-label uses, manufacturers may not market or promote such uses. However, companies may share truthful and not misleading information that is not inconsistent with the labeling, and the FDA has recently published a draft guidance with recommendations for how drug manufacturers can share scientifically sound and clinically relevant information on unapproved uses with health care providers so long as such presentations are not promotional.

If we are found to have promoted any off-label uses of our future approved products, or to have engaged in the promotion of an unapproved product candidate, we may become subject to significant liability. The U.S. federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of our future approved products, we could become subject to significant liability, which would materially adversely affect our business, results of operations, and financial condition.

Ongoing healthcare legislative and regulatory reform measures may adversely affect our business, results of operations, and financial condition.

The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could, among other things, prevent or delay marketing approval of our product candidate(s), restrict or regulate post-approval activities and affect our ability to profitably sell any product for which we obtain marketing approval.

The Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, or, collectively, the ACA, includes measures that have significantly changed the way healthcare is financed by both governmental and private insurers. There have been judicial, executive and congressional challenges and amendments to certain aspects of the ACA. For example, on July 4, 2025, the One Big Beautiful Bill Act, or the OBBBA, was signed into law, which narrowed access to ACA marketplace exchange enrollment and declined to extend the ACA enhanced advanced premium tax credits that expired at the end of 2025, which, among other provisions in the law, are anticipated to reduce the number of Americans with health insurance. The OBBBA also is expected to reduce Medicaid spending and enrollment by implementing work requirements for some beneficiaries, capping state-directed payments, reducing federal funding, and limiting provider taxes used to fund the program. Congress is considering proposed legislation intended to further reduce healthcare costs with alternatives to replace the expired ACA subsidies. We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of 2% per fiscal year, which began in 2013 and will remain in effect until 2032 unless additional Congressional action is taken.

Further, the current administration is pursuing policies to reduce regulations and expenditures across government agencies including at HHS, the FDA, the Centers for Medicare & Medicaid Services, or CMS, and related agencies. These actions, presently directed by executive orders or memoranda from the Office of Management and Budget, may propose policy changes that create additional uncertainty for our business. For example, the current administration has announced agreements with several pharmaceutical companies that require the drug manufacturers to offer, through a direct- to-consumer platform (TrumpRx), U.S. patients and Medicaid programs prescription drug Most-Favored Nation pricing equal to or lower than those paid in other developed nations, with additional mandates for direct-to-patient discounts and repatriation of foreign revenues. Other recent actions, for example, include (1) directing agencies to reduce agency workforce and cut programs; (2) directing HHS and other agencies to lower prescription drug costs through a variety of initiatives; (3) imposing tariffs on imported pharmaceutical products; and (4) as part of the Make America Healthy Again Commission's Strategy Report released in September 2025, working across government agencies to increase enforcement on direct-to-consumer pharmaceutical advertising. Additionally, the current administration recently called on Congress to enact "The Great Healthcare Plan," to codify and expand Most-Favored Nation pricing, lower government subsidies to private insurance companies, increase healthcare price transparency, expand pharmaceutical drugs available for over-the-counter purchase, and enact restrictions on pharmacy benefit manager payment methodologies, among other things. These actions and policies may significantly reduce U.S. drug prices, potentially impacting manufacturers' global pricing strategies and profitability, while increasing their operational costs and compliance risks. In June 2024, the U.S. Supreme Court's Loper Bright decision greatly reduced judicial deference to regulatory agencies, which could increase successful legal challenges to federal regulations affecting our operations. Congress may introduce and ultimately pass health care related legislation that could impact the drug approval process and make changes to the Medicare Drug Price Negotiation Program.

Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could materially and adversely affect our business, financial condition, results of operations and prospects. We expect that the healthcare reform measures that have been adopted and may be adopted in the future, may result in, among other things, more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product and could significantly harm our future revenues. 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 products, if approved. Changes in regulations, statutes or the interpretation of existing regulations could also impact our business in the future by requiring, for example, changes to our manufacturing arrangements; additions or modifications to product labeling; the recall or discontinuation of our products; or additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business. 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.

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

The ability of the FDA and comparable foreign regulatory authorities to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's and comparable foreign regulatory authorities' ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's and comparable foreign regulatory authorities' ability to perform routine functions. Average review times at the FDA and foreign regulatory authorities 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 national and foreign authorities also may slow the time necessary for review and/or approval by necessary government authorities, which would adversely affect our business.

For example, over the last several years including on October 1, 2025, 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, including as a result of current administration budget cutting activities and significant reductions in force across federal agencies, such as FDA and CMS. During the COVID-19 pandemic, moreover, FDA was required to prioritize resources, which resulted in the slowdown of certain operations including manufacturing facility inspections. If a prolonged government shutdown or slowdown occurs, or if future global health concerns prevent or delay the FDA or other comparable foreign regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other comparable foreign regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

We and the third parties with whom we work are subject to stringent and evolving U.S. and foreign laws, regulations, and rules, contractual obligations, industry standards, policies and other obligations related to data privacy and security. Our (or the third parties with whom we work) actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation (including class claims) and mass arbitration demands; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse business consequences.

In the ordinary course of business, we process sensitive data, and such data processing activities subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements and other obligations relating to data privacy and security. Further, our use of AI and/or machine learning technologies in the future may require additional privacy considerations. Sensitive, proprietary, personal, or confidential data and information could be leaked, disclosed, or revealed as a result of or in connection with our or our vendors' use, if any, of AI and/or machine learning technologies. The rapid development of artificial intelligence and/or machine learning technologies tools could render obsolete certain technologies or tools we currently use, or otherwise provide competitors with a technological edge. New or evolving legislation or regulations might impose restrictions on how AI and/or machine learning technologies can be used and impose various penalties for any noncompliance (such as disgorgement).

In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), and other similar laws (e.g., wiretapping laws). For example, HIPAA, as amended by HITECH, imposes specific requirements relating to the privacy, security, and transmission of individually identifiable protected health information. In addition, other federal and state laws establish and may in the future establish requirements for protecting the privacy and security of health information that is not protected by HIPAA.

Additionally, numerous U.S. states have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. These state laws allow for statutory fines for noncompliance. For example, the California Consumer Privacy Act of 2018, or CCPA, applies to personal data of California residents and requires businesses subject

to the CCPA to provide specific disclosures in privacy notices and respond to requests of such individuals to exercise certain privacy rights. Although there are minimum revenue or personal data processing thresholds for entities to be subject to many of these laws and there are limited exemptions for clinical trial data under the CCPA and similar U.S. state comprehensive privacy laws, such laws may impact (possibly significantly) our business activities depending on how they are interpreted, should we become subject to the CCPA or other such state comprehensive privacy laws in the future. In addition, similar laws are being considered in other states, as well as at the international, federal and local levels, and we expect more laws related to personal data to become effective in the future. These developments may further complicate compliance efforts and increase our legal risk and compliance costs.

Outside the United States, an increasing number of laws, regulations, and industry standards govern data privacy and security. For example, the European Union's General Data Protection Regulation, or EU GDPR, the United Kingdom's GDPR, or UK GDPR, Brazil's General Data Protection Law (Lei Geral de Proteção de Dados Pessoais, or LGPD) (Law No. 13,709/2018), and China's Personal Information Protection Law, or PIPL, impose strict requirements for processing personal data.

For example, under GDPR, companies may face private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests, temporary or definitive prohibitions on data processing and other corrective actions, or fines of up to the greater of 20 million Euros under the EU GDPR / 17.5 million pounds under the UK GDPR, or 4% of their worldwide annual revenue, whichever is higher.

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, or EEA, and the UK have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it generally believes are inadequate. Other jurisdictions may adopt or have already adopted similarly stringent data localization and cross-border data transfer requirements. 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 (including future clinical trials), the need to relocate part of or all of our business or data processing activities to other jurisdictions (such as Europe) 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. Other regulators, such as the United States Department of Justice, or US DOJ are also increasingly scrutinizing certain personal data transfers and have enacted certain cross-border data transfer prohibitions and restrictions that impact life sciences companies. Violations of the relevant US DOJ rule can lead to significant civil and criminal penalties and applies regardless of whether the data is anonymized, key-coded pseudonymized, de-identified or encrypted.

In addition to data privacy and security laws, we are and may become contractually subject to industry standards adopted by industry groups. We are also bound by other contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful.

We may also publish privacy policies, marketing materials, and other statements, such as compliance with certain certifications or self-regulatory principles, regarding data privacy and security. Regulators are increasingly scrutinizing these statements, and if these policies, materials, or statements are found to be deficient, lacking in transparency, deceptive, unfair, misleading, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators, or other adverse consequences.

Obligations related to data privacy and security (and individuals' data privacy expectations) are quickly changing, becoming increasingly stringent, and creating uncertainty. Additionally, these obligations are subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources and may necessitate changes to our services, information technologies, systems, and practices and to those of any third parties that process personal data on our behalf.

We may at times fail (or be perceived to have failed) in our efforts to comply with our data privacy and security obligations. Moreover, despite our efforts, our personnel or third parties with whom we work (such as contract research

organizations and clinical trial sites) may fail (or be perceived to have failed) to comply with such obligations, which could negatively impact our business operations. If we or the third parties with whom we work fail, or are perceived to have failed, to address or comply with applicable data privacy and security obligations, we could face significant consequences, including but not limited to, government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-action claims) and mass arbitration demands; additional reporting requirements and/or oversight; bans or restrictions on processing personal data (including clinical trial data); orders to destroy or not use personal data; and imprisonment of company officials. In particular, plaintiffs have become increasingly more active in bringing privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: interruptions or stoppages in our business operations (including, as relevant, clinical trials); inability to process sensitive data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our business model or operations.

Additional laws and regulations governing international operations could adversely affect our business, results of operations and financial condition.

If we further expand our operations outside of the United States, we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. The U.S. Foreign Corrupt Practices Act of 1977, as amended, or the FCPA, prohibits any U.S. individual or business from paying, offering, authorizing payment, or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate, and other related parties 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 certain 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.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

Various laws, regulations, and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. If we expand our presence outside of the United States, it will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain products and product candidates outside of the United States, which could limit our growth potential and increase our research and development costs.

The failure to comply with laws governing international business practices may result in substantial civil and criminal penalties and suspension or debarment from government contracting. The SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

We are subject to certain U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations. We can face serious consequences for violations.

We are subject to U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations, which are collectively referred to as Trade Laws. Among other things, Trade Laws prohibit companies and their employees, agents, clinical research organizations, contractors, and other partners from authorizing, promising, offering, providing, soliciting, or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. We have direct or indirect interactions with officials and employees of government authorities or government-affiliated hospitals, universities, and other organizations. We also expect our non-U.S. activities to increase over time. We may engage third parties for clinical trials and/or to obtain

necessary permits, licenses, patent registrations, and other regulatory approvals, and we can be held liable for the corrupt or other illegal activities of our personnel, agents, or partners, even if we do not explicitly authorize or have prior knowledge of such activities, and any training or compliance programs or other initiatives we undertake to prevent such activities may not be effective.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business.

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

We maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees, but this insurance may not provide adequate coverage against potential liabilities. However, we do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us.

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

Risks Related to Ownership of Our Common Stock

An active and liquid trading market for our common stock may not be sustained, or we may in the future fail to satisfy the continued listing requirements of Nasdaq and our stock may be delisted, and you may not be able to resell your shares of common stock at or above the public offering price, if at all.

Prior to our IPO in September 2025, there was no public market for shares of our common stock. Although our common stock is currently listed on the Nasdaq Global Market, we cannot assure you that an active trading market for our shares will be sustained. The lack of an active market may reduce the fair market value of your shares. Furthermore, an inactive market may also impair our ability to raise capital by selling shares of our common stock in the future and may impair our ability to enter into strategic collaborations or acquire companies or products by using our shares of common stock as consideration.

In addition, 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.

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

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

- variations in the level of expense related to the ongoing development of LB-102 or future development programs;

- results and timing of preclinical studies and ongoing and future clinical trials, or the addition or termination of any such clinical trials;
- the timing of payments we may make or receive under existing license and collaboration arrangements or the termination or modification thereof;
- our execution of any strategic transactions, including acquisitions, collaborations, licenses, or similar arrangements, and the timing and amount of payments we may make or receive in connection with such transactions;
- any intellectual property infringement lawsuit or opposition, interference, or cancellation proceeding in which we may become involved;
- recruitment and departures of key personnel;
- if our product candidate receives regulatory approval in the future, the terms of such approval, and market acceptance and demand for such products;
- regulatory developments affecting our product candidate or those of our competitors;
- global or regional public health emergencies, including any health epidemics and their residual effects, natural disasters, or major catastrophic events;
- adverse macroeconomic conditions or geopolitical events, including the conflict between Ukraine and Russia, high levels of inflation, heightened interest rates, and bank failures;
- the impacts of inflation and rising interest rates on our business and operations; and
- changes in general market and economic conditions.

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

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

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

- volatility and instability in the financial and capital markets;
- adverse macroeconomic conditions or geopolitical events, including any health epidemics and their residual effects, the conflict between Ukraine and Russia, high levels of inflation, heightened interest rates, and bank failures;
- announcements relating to our product candidate, including the results of clinical trials by us or our collaborators and the timing thereof;
- announcements by competitors that impact our competitive outlook;
- negative developments with respect to our product candidate, or similar products or product candidates with which we compete;
- developments with respect to patents or intellectual property rights;
- announcements of technological innovations, new product candidates, new products or new contracts by us or our competitors;
- announcements relating to strategic transactions, including acquisitions, collaborations, licenses, or similar arrangements;
- actual or anticipated variations in our operating results due to the level of development expenses and other factors;

- changes in financial estimates by equities research analysts and whether our earnings (or losses) meet or exceed such estimates;
- announcement or expectation of additional financing efforts and receipt, or lack of receipt, of funding in support of conducting our business;
- sales of our common stock by us, our insiders, or other stockholders, or issuances by us of shares of our common stock in connection with strategic transactions;
- expiration of market standoff or lock-up agreements;
- conditions and trends in the pharmaceutical, biotechnology, and other industries;
- recruitment and departures of key personnel;
- regulatory developments within, and outside of, the United States, including changes in the structure of health care payment systems;
- litigation or arbitration;
- general economic, political, and market conditions and other factors; and
- the occurrence of any of the risks described in this section titled "Risk Factors".

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

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

We have never declared or paid cash dividends on our common stock. We currently intend to retain all available funds and any future earnings to support operations and to finance the growth and development of our business. We do not intend to declare or pay any cash dividends on our capital stock in the foreseeable future. As a result, any investment return on our common stock will depend upon increases in the value for our common stock, which is not certain.

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

Based on the beneficial ownership of our common stock as of December 31, 2025, our directors and executive officers, holders of 5% or more of our capital stock and their respective affiliates beneficially own a significant percentage of our outstanding common stock. These stockholders, if they act together, will be able to influence our management and affairs and 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 concentration of ownership may have the effect of delaying or preventing a change in control of our company and might affect the market price of our common stock.

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

We could be an emerging growth company for up to five years following the completion of our IPO, although circumstances could cause us to lose that status earlier. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of our IPO, (b) in which we have total annual gross revenue of at least $1.235 billion and (c) in which we are deemed to be a large accelerated filer, which requires the market value of our common stock that is held by non-affiliates to exceed $700.0 million as of the prior June 30th, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period. 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.

Under the JOBS Act, emerging growth companies also can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to avail ourselves of this exemption, and, as a result, our operating results and financial statements may not be comparable to the operating results and financial statements of companies who have adopted the new or revised accounting standards.

We also are a "smaller reporting company," meaning that the market value of our stock held by non-affiliates is less than $700.0 million and our annual revenue is less than $100.0 million during the most recently completed fiscal year. We may continue to be a smaller reporting company if either (i) the market value of our stock held by non-affiliates is less than $250.0 million or (ii) our annual revenue is less than $100.0 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700.0 million. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our annual report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

Conflicts of interest may arise because some members of our board of directors are representatives of our principal stockholders.

Certain of our principal stockholders or their affiliates are venture capital funds or other investment vehicles that could invest in entities that directly or indirectly compete with us. As a result of these relationships, when conflicts arise between the interests of the principal stockholders or their affiliates and the interests of other stockholders, members of our board of directors that are representatives of the principal stockholders may not be disinterested.

Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.

If our stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after the lock-up and other legal restrictions on resale lapse, the trading price of our common stock could decline.

Certain holders of our common stock have rights, subject to some conditions, to require us to file registration statements covering the sale of their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We have registered the offer and sale of all shares of common stock that we may issue under our equity compensation plans, and those shares are available for sale in the open market, unless such shares are subject to vesting restrictions with us or the lock-up restrictions described above. Once we register the offer and sale of shares for the holders of registration rights, they can be freely sold in the public market upon issuance, subject to the lock-up agreements.

In addition, we expect that significant additional capital may be needed in the future to continue our planned operations, including conducting clinical trials, commercialization efforts, expanded research and development activities and costs associated with operating a public company. To raise capital, in the future, we may issue additional shares of our common stock or other equity or debt securities convertible into common stock in connection with a financing, acquisition, litigation settlement, employee arrangements or otherwise. Any such issuance could result in substantial dilution to our existing stockholders and could cause our stock price to decline.

Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of our company more difficult, limit attempts by our stockholders to replace or remove our current management and limit the market price of our common stock.

Provisions in our amended and restated certificate of incorporation and our amended and restated bylaws may have the effect of delaying or preventing a change of control or changes in our board of directors and management. Our amended and restated certificate of incorporation and amended and restated bylaws will include provisions that:

- authorize our board of directors to issue, without further action by the stockholders, shares of undesignated preferred stock with terms, rights, and preferences determined by our board of directors that may be senior to our common stock;
- require that any action to be taken by our stockholders be effected at a duly called annual or special meeting and not by written consent;
- specify that special meetings of our stockholders can be called only by directors representing a majority of the total authorized size of our board of directors, the chairperson of our board of directors, or our chief executive officer;
- establish an advance notice procedure for stockholder proposals to be brought before an annual meeting, including proposed nominations of persons for election to our board of directors;
- establish that our board of directors is divided into three classes, with each class serving three-year staggered terms;
- prohibit cumulative voting in the election of directors, 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 our directors may be removed for cause only upon the vote of at least 66 2/3% of our outstanding shares of voting stock;
- provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum; and
- require the approval of our board of directors or the holders of at least 66 2/3% of our outstanding shares of voting stock to amend our bylaws and certain provisions of our certificate of incorporation.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, or DGCL, which generally, subject to certain exceptions, prohibits a Delaware corporation from engaging in any of a broad range of business combinations with any "interested" stockholder for a period of three years following the date on which the stockholder became an "interested" stockholder. Any of the foregoing provisions could limit the price that investors might be willing to pay in the future for shares of our common stock, and they could deter potential acquirers of our company, thereby reducing the likelihood that holders of our common stock would receive a premium for their shares of our common stock in an acquisition.

Our amended and restated certificate of incorporation provide that the Court of Chancery of the State of Delaware and the federal district court for the District of Delaware of the United States will be 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 provide that 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 asserting a breach of fiduciary duty;

- any action asserting a claim against us arising under the DGCL, our amended and restated certificate of incorporation, or our amended and restated bylaws;
- any action seeking to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation, or our amended and restated bylaws;
- any action to which the DGCL confers jurisdiction on the Court of Chancery of the State of Delaware; and
- any action asserting a claim against us that is governed by the internal-affairs doctrine.

This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. Additionally, investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation will further provide that the federal district courts of the United States will be 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 and several state trial courts have enforced such provisions and required that suits asserting Securities Act claims be filed in federal court, there is no guarantee that courts of appeal will affirm the enforceability of such provisions and 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 the provisions may not be enforced by a court in those other jurisdictions. 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 litigating Securities Act claims in state court, or both state and federal court, which could seriously harm our business, results of operations, and financial condition.

This exclusive forum provision may result in increased costs to stockholders to bring a claim. Further, this exclusive forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or 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

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

We have incurred significant losses during our history and do not expect to become profitable in the near future, and we may never achieve profitability. As of December 31, 2025, we had federal net operating loss, or NOL, carryforwards of $70.3 million and state gross NOL carryforwards of $41.7 million. The federal NOL carryforwards, if not utilized, will begin to expire in 2036. The state NOL carryforwards are expected to begin to expire in 2036, although not all states conform to the federal NOL carryforward period and occasionally limit the use of NOLs for a period of time. As of December 31, 2025, we had federal research and development credits of approximately $4.9 million. The research and development credits, if not utilized, will expire between 2036 through 2045. Certain of these NOL carryforwards could expire unused and be unavailable to offset future income tax liabilities. Under the Internal Revenue Code of 1986, as amended, or the Code, federal NOL carryforwards arising in taxable years beginning after December 31, 2017 will not expire and may be carried forward indefinitely, but the deductibility of such federal NOL carryforwards in a taxable year is generally limited to no more than 80% of current year taxable income (with certain adjustments in such year).

In addition, under Sections 382 and 383 of the Code, if a corporation undergoes an "ownership change," generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three-year period, the corporation's ability to use its pre-change NOL carryforwards and certain other pre-change tax attributes (such as research and development credits) to offset its post-change income or taxes may be limited. We have not completed a Section 382 study to assess whether one or more ownership changes have occurred since our formation, due to the complexity and cost associated with such a study. In addition, we also may experience ownership changes in

the future including as a result of subsequent changes in our stock ownership, some of which may be outside of our control. As a result, if we undergo (or already have undergone) an ownership change, and our ability to use our pre-change NOL carryforwards and other pre-change tax attributes (such as research and development credits) to offset our post-change income or taxes is limited, it could harm our future results of operations by effectively increasing our future tax obligations. Similar provisions of state tax law also may apply to limit our use of accumulated state tax attributes. In addition, at the state level, there may be periods during which the use of net operating losses is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. Even if we attain profitability, we may be unable to use all or a material portion of our net operating losses and other tax attributes, which could adversely affect our future cash flows. As a result of the foregoing, we have a full valuation allowance for deferred tax assets, including our NOL carryforwards.

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

The tax regimes we are subject to or operate under, including with respect to income and non-income taxes, are unsettled and may be subject to significant change. Changes in tax laws, regulations, or rulings, or changes in interpretations of existing laws and regulations, could materially adversely affect our company. For example, on July 4, 2025, the U.S. government passed the OBBBA, which made permanent certain of the tax law changes originally enacted under previous tax reform legislation, in addition to other changes that may impact our tax liability. For example, the OBBBA reinstated immediate expensing of certain research and experimental expenses incurred in tax years beginning after December 31, 2025 if incurred in the United States (though the requirement to amortize foreign research and experimental expenses over 15 years remains unchanged). In addition, previous tax reform legislation includes provisions that impact the U.S. federal income taxation of certain corporations, including imposing a 1% excise tax on corporations that repurchase their stock in certain transactions. Future guidance from the Internal Revenue Service and other tax authorities with respect to this and other legislation may affect us, and certain aspects thereof could be repealed or modified in future legislation.

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

Global economic and business activities continue to face widespread uncertainties, and global credit and financial markets have experienced extreme volatility and disruptions in the past several years, including severely diminished liquidity and credit availability, rising inflation and monetary supply shifts, tariffs, rising interest rates, bank failures, labor shortages, declines in consumer confidence, declines in economic growth, increases in unemployment rates, recession risks, and uncertainty about economic and geopolitical stability (for example, related to the ongoing Russia-Ukraine war). For example, there is currently significant uncertainty about the future relationship between the United States and various other countries, including, without limitation, China, with respect to trade policies, treaties, tariffs, taxes, and other limitations on cross-border operations.

Current or future tariffs could result in increased research and development expenses, including with respect to increased costs associated with active pharmaceutical ingredients, raw materials, laboratory equipment and research materials and components. In addition, such tariffs could increase our supply chain complexity and could also potentially disrupt our existing supply chain. Trade restrictions affecting the import of materials necessary for clinical trials could result in delays to our development timelines. Increased development costs and extended development timelines could place us at a competitive disadvantage compared to companies operating entirely domestically or in regions with more favorable trade relationships and could reduce investor confidence, negatively impacting our ability to secure additional financing on favorable terms or at all. In addition, as we advance toward commercialization in the future, tariffs and trade restrictions could hinder our ability to establish cost-effective production capabilities, negatively impacting our growth prospects.

The complexity of announced or future tariffs may also increase the risk that we or our customers or suppliers may be subject to civil or criminal enforcement actions in the United States or foreign jurisdictions related to compliance with trade regulations. Foreign governments may also adopt non-tariff measures, such as procurement preferences or informal disincentives to engage with, purchase from or invest in U.S. entities, which may limit our ability to compete internationally and attract non-U.S. investment, employees, customers and suppliers. Foreign governments may also take other retaliatory actions against U.S. entities, such as decreased intellectual property protection, increased enforcement actions or delays in regulatory approvals, which may result in heightened international legal and operational risks. In addition, the United States and other governments have imposed and may continue to impose additional sanctions, such

as trade restrictions or trade barriers, which could restrict us from doing business directly or indirectly in or with certain countries or parties and may impose additional costs and complexity to our business.

Trade disputes, tariffs, restrictions and other political tensions between the United States and other countries may also exacerbate unfavorable macroeconomic conditions including inflationary pressures, foreign exchange volatility, financial market instability and economic recessions or downturns. The ultimate impact of current or future tariffs and trade restrictions remains uncertain and could materially and adversely affect our business, financial condition, results of operations and prospects. While we actively monitor these risks, any prolonged economic downturn, escalation in trade tensions or deterioration in international perception of U.S.-based companies could materially and adversely affect our business, ability to access the capital markets or other financing sources, results of operations, financial condition and prospects.

The extent of the impact of these conditions on our operational and financial performance, including our ability to execute our business strategies and initiatives in the expected timeframe, as well as that of third parties upon whom we rely, will depend on future developments which are uncertain and cannot be predicted. There can be no assurance that further deterioration in economic or market conditions will not occur, or how long these challenges will persist. If the current equity and credit markets deteriorate, or do not improve, it may make any necessary debt or equity financing more difficult, more costly, and more dilutive. Furthermore, our stock price may decline due in part to the volatility of the stock market and the general economic downturn.

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

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

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

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

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

We are not currently required to comply with the rules of the SEC implementing Section 404 of the Sarbanes-Oxley Act and are therefore not required to make a formal assessment of the effectiveness of our internal control over financial reporting for that purpose. Upon becoming a public company, we are required to comply with the SEC's rules implementing Sections 302 and 404 of the Sarbanes-Oxley Act, which requires management to certify financial and other information in our quarterly and annual reports and provide an annual management report on the effectiveness of internal control over financial reporting. Although we are required to disclose changes made in our internal control over financial reporting on a quarterly basis, we are not be required to make our first annual assessment of our internal control over financial reporting until our second annual report on Form 10-K. However, as an emerging growth company, our independent registered public accounting firm is not required to formally attest to the effectiveness of our internal control over financial reporting until the later of the year following our first annual report required to be filed with the SEC or the date we are no longer an emerging growth company. 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 may 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 currently use a third-party internal audit function. To comply with the requirements of being a public company, we have undertaken various actions, and will need to take additional actions, such as implementing numerous internal controls and procedures and hiring additional accounting or internal audit staff or consultants. Additionally, in connection with the preparation of our financial statements for the year ended December 31, 2025, material weaknesses were identified in the design and operating effectiveness of our internal control over financial reporting. If we are unable to remediate these material weaknesses, or we identify more material weaknesses that we are not able to timely remediate to meet the applicable compliance deadline for the disclosure and attestation requirements of Section 404 of the Sarbanes-Oxley Act, or if our independent registered public accounting firm is unable to express an unqualified opinion as to the effectiveness of our internal control over financial reporting once we are no longer an emerging growth company, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock could be negatively affected, and we could become subject to investigations by the stock exchange on which our securities are listed, the SEC or other regulatory authorities, which could require additional financial and management resources. In addition, if we fail to remedy any material weakness, our financial statements could be inaccurate, and we could face restricted access to capital markets.

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

As a public company, we must design our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the SEC. Any disclosure controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. For example, our directors or executive officers could inadvertently fail to disclose a new relationship or arrangement causing us to fail to make any related party transaction disclosures. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected. In addition, we do not have a formal risk management program for identifying and addressing risks to our business in other areas.

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

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

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

Risk Management and Strategy

We have implemented and maintain various information security processes designed to identify, assess and manage material risks from cybersecurity threats to our critical computer networks, third party hosted services, communications systems, hardware and software, and our critical data, including intellectual property, confidential information that is proprietary, strategic or competitive in nature, and clinical trial data, or Information Systems and Data.

Our fractional Chief Information Officer ("CIO"), along with our legal and information security functions, help identify, assess and manage the Company's cybersecurity threats and risks. This group works to identify and assess risks from cybersecurity threats by monitoring and evaluating our threat environment using various methods including, for example manual and automated tools, analyzing reports of threats and actors, evaluating our and our industry's risk profile, evaluating threats reported to us, internal and external audits, conducting threat assessments for internal and external threats, third party threat assessments, conducting vulnerability assessments designed to identify vulnerabilities, and use of external intelligence feeds.

Depending on the environment, we implement and maintain various technical, physical, and organizational measures, processes, standards or policies designed to manage and mitigate material risks from cybersecurity threats to our Information Systems and Data, including, for example those related to: incident response, incident detection and response, data protection, access controls, physical security, systems monitoring, and employee training.

Our assessment and management of material risks from cybersecurity threats are integrated into the Company's overall risk management. For example, (1) cybersecurity risk is addressed as a component of the Company's enterprise risk management program; (2) the IT department works with management to prioritize our risk management processes and mitigate cybersecurity threats that are more likely to lead to a material impact on our business; and (3) our senior management evaluates material risks from cybersecurity threats and reports to the audit committee of the board of directors. The board of directors evaluates our overall enterprise risk.

We use third-party service providers to assist us in our efforts to identify, assess, and manage material risks from cybersecurity threats, including for example threat intelligence service providers, cybersecurity consultants, cybersecurity software providers, managed cybersecurity service providers, and dark web monitoring services.

We use third-party service providers to perform a variety of functions throughout our business, such as application providers and hosting companies. Depending on the nature of the services provided, the sensitivity of the Information Systems and Data at issue, and the identity of the provider, our vendor management process may involve different levels of assessment designed to help identify cybersecurity risks associated with a provider and impose contractual obligations related to cybersecurity on the provider.

For a description of the risks from cybersecurity threats that may materially affect the Company and how they may do so, see our risk factors under Part 1. Item 1A. Risk Factors in this Annual Report on Form 10-K, including "*If our information technology systems or those of third parties with whom we work, or our data are or were compromised, we*

could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse consequences".

Governance

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

Our cybersecurity risk assessment and management processes are implemented and maintained by certain Company management, including the Information Technology Manager (IT Manager) and the fractional CIO who have over 30 years of combined experience addressing cybersecurity related issues through prior work experience.

The IT Manager and fractional CIO are responsible for hiring appropriate personnel, helping to integrate cybersecurity risk considerations into the Company's overall risk management strategy, and communicating key priorities to relevant personnel. The IT Manager, along with the fractional CIO, are responsible for approving budgets, helping prepare for cybersecurity incidents, approving cybersecurity processes, and reviewing security assessments and other security-related reports.

Our cybersecurity incident response plan is designed to escalate certain cybersecurity incidents to members of management depending on the circumstances, including the CEO, Chief Operating and Business Officer, General Counsel, and Senior Vice President of Finance who work with the Company's incident responders in an effort to help the Company mitigate and remediate cybersecurity incidents of which they are notified. In addition, the Company's incident response plan includes reporting to the audit committee of the board of directors for certain cybersecurity incidents.

The audit committee receives periodic reports from the Senior Vice President of Finance concerning the Company's overall cybersecurity posture. The audit committee also receives various reports, summaries or presentations related to cybersecurity threats, risk and mitigation.

Item 2. Properties.

Our principal office is located at One Pennsylvania Plaza, Suite 1025, New York, NY 10119, where we lease approximately 8,900 square feet of office space under a lease that will expire in 2032. In November 2025, we entered into an amendment to our lease providing for approximately 4,600 square feet of additional office space through March 2032. We believe that our existing facility is adequate to meet our current needs, and that suitable additional alternative spaces will be available in the future on commercially reasonable terms.

Item 3. Legal Proceedings.

From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. We do not have any pending litigation that, separately or in the aggregate, would, in the opinion of management, have a material adverse effect on our results of operations, financial condition, or cash flows.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

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

Market Information

Our common stock trades under the symbol "LBRX" on the Nasdaq Global Market and began trading on September 11, 2025. Prior to that date, there was no public trading market for our common stock.

Holders of Our Common Stock

As of March 23, 2026, there were approximately 360 holders of record of shares of our common stock. 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.

Dividend Policy

We have never declared or paid, and do not anticipate declaring or paying in the foreseeable future, any cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings to support our operations and finance the growth and development of our business. Any future determination related to our dividend policy will be made at the discretion of our board of directors and will depend upon, among other factors, our results of operations, financial condition, capital requirements, contractual restrictions, business prospects and other factors our board of directors may deem relevant.

Securities Authorized for Issuance under Equity Compensation Plans

The information required by Item 5 of this Annual Report regarding equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report.

Recent Sales of Unregistered Equity Securities

Issuances Pursuant to our Equity Plans

Prior to filing our registration statement on Form S-8 in September 2025, we granted stock options to employees under our 2023 Stock Incentive Plan, covering an aggregate of 44,431 shares of common stock, at a weighted average exercise price of $36.00 per share.

Issuances Outside of Our Equity Plans

On November 10, 2025, we granted to an employee an option to purchase 90,000 shares of our common stock. This option was made as an inducement material to such individual's acceptance of an offer of employment with us in accordance with Nasdaq Listing Rule 5635(c)(4). We intend to file a registration statement on a Form S-8 to register the shares of common stock underlying this inducement award prior to the time at which the award becomes exercisable.

On December 10, 2025, we granted to an employee an option to purchase 195,000 shares of our common stock. This option was made as an inducement material to such individual's acceptance of an offer of employment with us in accordance with Nasdaq Listing Rule 5635(c)(4). We intend to file a registration statement on a Form S-8 to register the shares of common stock underlying this inducement award prior to the time at which the award becomes exercisable.

On January 9, 2026, we granted to two employees options to purchase an aggregate of 175,000 shares of our common stock. These options were made as an inducement material to each individual's acceptance of an offer of employment with us in accordance with Nasdaq Listing Rule 5635(c)(4). We intend to file a registration statement on a Form S-8 to register the shares of common stock underlying these inducement awards prior to the time at which the awards becomes exercisable.

On February 10, 2026, we granted to an employee an option to purchase 140,000 shares of our common stock. This option was made as an inducement material to such individual's acceptance of an offer of employment with us in accordance with Nasdaq Listing Rule 5635(c)(4). We intend to file a registration statement on a Form S-8 to register the shares of common stock underlying this inducement award prior to the time at which the award becomes exercisable.

None of the foregoing transactions involved any underwriters, underwriting discounts or commissions, or any public offering. The sales of the above securities were deemed to be exempt from registration under the Securities Act in reliance on Section 4(a)(2) of the Securities Act (and/or Regulation D or Regulation S promulgated thereunder) or Rule 701 promulgated under Section 3(b) of the Securities Act as transactions by an issuer not involving any public offering or pursuant to benefit plans and contracts relating to compensation as provided under Rule 701.

Use of Proceeds from our Public Offering of Common Stock

On September 10, 2025, our registration statement on Form S-1 was declared effective by the SEC for our IPO. At the closing of our IPO on September 12, 2025, we sold 21,850,000 shares of common stock, which included the exercise in full by Leerink Partners LLC, Piper Sandler & Co. and Stifel, Nicolaus & Company, Incorporated of their over-allotment option to purchase 2,850,000 additional shares, at an initial public offering price of $15.00 per share and received gross proceeds of $327.75 million, which resulted in aggregate net proceeds to us of approximately $302.3 million, after deducting underwriting discounts, commissions and offering-related transaction costs. There has been no material change in the planned use of proceeds from that described in the final prospectus for our IPO filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act.

Issuer Purchases of Equity Securities

None.

Item 6. Reserved.

Not Applicable.

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 the related notes included elsewhere in this Annual Report on Form 10-K. This discussion and analysis and other parts of this Annual Report on Form 10-K contain forward-looking statements based upon current beliefs, plans and expectations related to future events and our future financial performance that involve risks, uncertainties and assumptions, such as statements regarding our intentions, plans, objectives and expectations for our business. Our actual results and the timing of selected events could differ materially from those described in or implied by these forward-looking statements as a result of several factors, including those set forth in the section titled "Risk Factors" in Part I, Item 1A of this Annual Report on Form 10-K. See also the section titled "Special Note Regarding Forward-Looking Statements."

Overview

We are a late-stage biopharmaceutical company developing novel therapies for the treatment of a wide range of neuropsychiatric disorders including schizophrenia, bipolar depression, adjunctive treatment of major depressive disorder and other diseases. We are building a pipeline that leverages the broad therapeutic potential of our lead product candidate, LB-102, which we believe has the potential to be the first benzamide antipsychotic drug approved for neuropsychiatric disorders in the United States. LB-102 is currently in late-stage clinical development for schizophrenia and bipolar depression. We are also planning to conduct a Phase 2 clinical trial evaluating LB-102 as an adjunctive treatment in major depressive disorder, or MDD. LB-102 is a new chemical entity and a methylated derivative of amisulpride, a second-generation antipsychotic drug approved in over 50 countries, not including the United States, because the development and regulatory requirements of the U.S. Food and Drug Administration, or FDA, for amisulpride were incompatible with patent coverage on the drug. Amisulpride is a generic drug that has been extensively used in clinical practice following its initial approval in France in the 1980s, generating at least two million monthly prescriptions in 2023 in a subset of 16 continental European countries. Among these European prescriptions for amisulpride, our data suggest that approximately 60% are for schizophrenia and schizoaffective disorders, approximately 20% are for mood disorders, approximately 14% are for anxiety, and the remainder are for a variety of other indications.

We designed LB-102 to address the limitations of amisulpride with the aim to create a product candidate with the potential for a differentiated therapeutic profile and strong intellectual property protection. We believe LB-102's mechanism of action, data from our recently completed Phase 2 trial (NOVA-1) of LB-102 in acute schizophrenia, and the heritage of clinical experience with amisulpride support the continued development of LB-102 in both psychosis and mood disorders. In the future, additional expansion opportunities for LB-102 may include predominantly negative symptoms of schizophrenia, Alzheimer's disease psychosis and agitation, as well as other neuropsychiatric diseases. We believe that LB-102, if approved, can become a mainstay of psychiatric practice by offering a potentially attractive alternative to branded and generic therapeutics for the treatment of schizophrenia, bipolar depression, adjunctive MDD and other neuropsychiatric diseases, given the compelling balance of clinical activity and tolerability observed to date.

The U.S. market for branded antipsychotic drugs was approximately $12 billion as of 2024. Antipsychotics that have expanded beyond schizophrenia and into mood disorder indications have realized substantial increases in revenue. Despite the widespread use of generic antipsychotic drugs, several of these branded drugs each generate U.S. sales in excess of $1 billion annually. Additionally, while available therapeutics to treat schizophrenia, bipolar depression, and MDD demonstrate clinical benefit, a significant unmet need remains for a treatment that delivers a more favorable risk–benefit profile by balancing tolerability with rapid onset and sustained, clinically meaningful efficacy with once-daily dosing. This includes addressing persistent residual symptoms—across both psychosis and mood disorders—that continue to impair functioning despite available therapies, underscoring the opportunity for improvement in the management of these conditions.

For additional information regarding our business, see "Business" in Part I, Item 1 of this Annual Report on Form 10-K.

Pipeline Programs and Operational Updates

Pipeline Programs

We are building a pipeline that leverages the broad therapeutic potential of our lead product candidate, LB-102, which we believe has the potential to be the first benzamide antipsychotic drug approved for neuropsychiatric disorders in the United States. We have initiated our Phase 3 trial (NOVA-2) of LB-102 in patients with acute schizophrenia and our Phase 2 trial (ILLUMINATE-1) of LB-102 in patients with bipolar depression. We plan to initiate a Phase 2 trial of LB-102 for the adjunctive treatment of MDD in early 2027. Data from the Phase 3 trial in schizophrenia is expected in the second half of 2027, data from the Phase 2 trial in bipolar disorder is expected in the first quarter of 2028 and data from the Phase 2 trial in adjunctive MDD is expected in the first half of 2029.

- In January 2025, we reported positive results from a robust 359 patient Phase 2 trial of LB-102 in schizophrenia. The trial met the primary endpoint, demonstrating statistically significant reduction from baseline in the Positive and Negative Syndrome Scale (PANSS) total score at 4 weeks at all dose levels compared to placebo. In this trial, LB-102 was observed to be generally well-tolerated.
- In March 2025, we presented additional positive data from our Phase 2 trial at the 2025 Annual Congress of the Schizophrenia International Research Society (SIRS) demonstrating that treatment with LB-102 resulted in a positive shift in disease severity as measured by mean change from baseline in Clinical Global Impression of Severity (CGI-S) scores.
- In October 2025, we presented three posters featuring new and previously reported analyses from our Phase 2 clinical trial of LB-102 in acute schizophrenia at the 38th European College of Neuropsychopharmacology (ECNP) Congress.
- In January 2026, we announced the initiation of the Phase 2 trial (ILLUMINATE-1) evaluating the efficacy and safety of LB-102 in patients with bipolar depression.

Since our inception in 2015, we have devoted substantially all of our resources to the research and development of LB-102 by conducting clinical trials and preclinical studies and recruiting management and technical staff to support these operations. To date, we have funded our operations primarily through the aggregate gross proceeds of approximately $549.5 million from the sales of our redeemable convertible preferred stock, common stock, and convertible notes and the proceeds of our initial public offering, or IPO, and proceeds from our private placement. On September 12, 2025, we closed the IPO and issued 21,850,000 shares of common stock at a price to the public of $15.00 per share, including 2,850,000 shares issued upon the exercise in full of the underwriters' over-allotment option to purchase additional shares. We received gross proceeds of $327.8 million. Net proceeds were $302.3 million, after deducting underwriting commissions and other offering costs totaling $25.4 million. In February 2026, we received gross proceeds of approximately $100.0 million, before deducting any transaction-related expenses from our private placement.

We have not generated any revenue from product sales and we have incurred recurring losses since our inception. Our net losses were $25.2 million and $63.1 million for the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025, we had an accumulated deficit of $129.5 million. We expect to continue to generate operating losses

and negative operating cash flows for the foreseeable future. We anticipate that our operating expenses and capital expenditures will increase substantially with our ongoing activities, particularly as we:

- continue to progress the clinical development of LB-102 in acute schizophrenia, bipolar depression, adjunctive MDD and other indications;
- advance additional product candidates through clinical development;
- require the manufacture of larger quantities of LB-102 and any additional product candidates to support future clinical trials or potential commercialization;
- seek marketing authorizations for LB-102 and any of our future product candidates that successfully complete clinical development, if any;
- acquire or license other product candidates or technologies;
- make milestone, royalty, or other payments under our current royalty agreements or any future license agreements;
- obtain, maintain, protect, and enforce our intellectual property portfolio;
- seek to attract and retain new and existing skilled personnel; and
- add operational, legal, financial, and management information systems and personnel to support our product development and clinical execution, as well as to support our transition to a public company.

We will not generate any revenue from product sales unless and until we successfully complete clinical development and obtain regulatory approval for one or more of our product candidates. If we obtain regulatory approval for any of our product candidates, we expect to incur significant expenses related to developing our internal commercialization capability to support product sales, marketing, and distribution. As a result, we will need substantial additional funding to support our operating activities as we advance our product candidates through clinical development, seek regulatory approval, and prepare for and, if any of our product candidates are approved, proceed to commercialization. Until such time, if ever, as we can generate substantial revenue from product sales to support our cost structure, we expect to finance our operating activities through a combination of public or private sales of equity, government or private party grants, debt financings or other capital sources, including potential collaborations with other companies or other strategic transactions. Adequate funding may not be available to us on acceptable terms, or at all.

If we are unable to obtain funding, we will be forced to delay, reduce, or eliminate some or all of our research and development programs, product portfolio expansion, or commercialization efforts, which could adversely affect our business prospects, or we may be unable to continue operations. Although we continue to pursue these plans, there is no assurance that we will be successful in obtaining sufficient funding on terms acceptable to us to fund continuing operations, if at all.

As of December 31, 2025, we had cash, cash equivalents and marketable securities of $295.2 million, which does not include net proceeds from our $100 million private placement in February 2026. Based on our current plans, we believe that our existing cash, cash equivalents and marketable securities, including net proceeds from our private placement, will be sufficient to meet our anticipated operating and capital expenditure requirements into the second quarter of 2029. See "—Liquidity and Capital Resources."

Royalty Agreements

In August 2023, contemporaneously with the closing of the Series C financing, we entered into several Amended and Restated Royalty Agreements with certain of our existing investors, co-founders, former and current directors, and former and current executive officers, including Zachary Prensky, Andrew Vaino, Ph.D., and Marc Panoff, none of whom were new investors of our Series C preferred stock. We received no consideration as part of the Amended and Restated Royalty Agreements. Pursuant to the Amended and Restated Royalty Agreements, we are obligated to pay royalties to all of the holders in an aggregate amount up to 2.75% of net sales arising from LB-102 worldwide through December 31, 2035. Thereafter, we are obligated to pay royalties to such holders in an aggregate amount up to 3.25% in perpetuity. Net sales are defined in these agreements as the gross payments received on total commercial sales of LB-102 less certain standard deductions, whether received by us or any licensee of LB-102. For additional information, see "Item

1. Business—License and Other Agreements—Royalty Agreements." As of December 31, 2025, certain of our former and current officers and their affiliates held 1.13% of the future royalties.

Components of Results of Operations

Revenue

To date, we have not recognized any revenues, including revenues from product sales. We do not expect to generate any revenue from the sale of products in the foreseeable future. If our development efforts for LB-102 or any future product candidates are successful and result in regulatory approval, or license agreements with third parties, we may generate revenue in the future from product sales. However, there can be no assurance as to when we will generate such revenue, if at all.

Operating Expenses

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for the development of LB-102, which include:

- personnel expenses, including salaries, benefits, and stock-based compensation expense for our employees engaged in research and development functions;
- expenses incurred in connection with the preclinical and clinical development of LB-102, including under agreements with clinical sites and CROs;
- formulation costs and chemistry, manufacturing and controls, or CMC, costs including formulation and active pharmaceutical ingredients, process development, analytical and quality infrastructure build-out, and validation support;
- expenses incurred under agreements with consultants engaged in research and development functions; and
- expenses related to regulatory affairs.

We expense research and development costs in the periods in which they are incurred. Costs for certain activities are recognized based on an evaluation of the progress to completion of specific tasks, using information provided to us by our vendors and analyzing the progress of our clinical trials or other services performed. Significant judgment and estimates are made in determining the accrued expense balances at the end of any reporting period.

Research and development activities are central to our business model. We expect our research and development expenses to increase substantially for the foreseeable future as we advance LB-102 and any of our future product candidates into and through later stage clinical trials, pursue regulatory approval of our product candidates, build our operational and commercial capabilities for supplying and marketing our products, if approved, and expand our pipeline of product candidates.

The process of conducting the necessary clinical research to obtain regulatory approval is costly and time-consuming. Furthermore, product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. The actual probability of success for our product candidates may be affected by a variety of factors, including the safety and efficacy of our product candidates, conduct of clinical trials, investment in our clinical programs, competition, manufacturing capability, and commercial viability. We may never succeed in achieving regulatory approval for any of our product candidates. As a result of the uncertainties discussed above, we are unable to determine the duration and completion of costs of our research and development projects or if, when, and to what extent we will generate revenue from the commercialization and sale of LB-102 or any future product candidates, if approved by the FDA and other applicable regulatory authorities.

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

- the timing and progress of our clinical development activities;
- the number and scope of preclinical and clinical programs we decide to pursue;

- the amount and timing of any milestone payment due under an existing, or any future, license or collaboration agreement or asset acquisition;
- the cost and timing of manufacturing our product candidates;
- the number of patients that participate in our clinical trials, and per participant clinical trial costs;
- the number and duration of clinical trials required for approval of our product candidates;
- the number of sites included in our clinical trials, and the locations of those sites;
- delays or difficulties in adding trial sites and enrolling participants in our clinical trials;
- patient drop-out or discontinuation rates;
- potential additional safety monitoring requested by regulatory authorities;
- the phase of development of our product candidates;
- the efficacy and safety profile of our product candidates;
- the timing, receipt, and terms of any approvals from applicable regulatory authorities, including the FDA and non-U.S. regulators;
- maintaining a continued acceptable safety profile of our product candidates following approval, if any, of our product candidates;
- hiring and retaining additional personnel such as clinical, quality control, scientific, regulatory, commercial, and administrative;
- maintain, expand, and protect our intellectual property portfolio;
- establish sales, marketing, distribution, manufacturing, supply chain, and other commercial infrastructure in the future to commercialize various products for which we may obtain regulatory approval;
- changes in the competitive outlook;
- the extent to which we establish additional strategic collaborations or other arrangements; and
- the impact of any business interruptions to our operations or to those of the third parties with whom we work.

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

We also expect to incur significant manufacturing costs as our CDMOs develop scaled commercial manufacturing processes. However, we do not believe that it is possible at this time to accurately project expenses through commercialization. There are numerous factors associated with the successful commercialization of LB-102 or any future product candidates, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development. Additionally, future commercial and regulatory factors beyond our control will impact our clinical development programs and plans.

General and Administrative Expenses

General and administrative expenses consist primarily of:

- personnel expenses, including salaries, benefits, and stock-based compensation, for personnel in our executive, finance, corporate and business development, and administrative functions;
- professional fees for legal, patent, accounting and audit, recruiting, information technology, and tax;
- consulting services including fees paid to our board of directors; and
- other expenses including travel expenses, rent expense, and other operating costs.

We expect that our general and administrative expenses will increase in the future as we expand our headcount to support our continued research and development of our product candidates. We also expect to incur increased expenses associated with operating as a public company including:

- costs related to accounting, audit, legal, compliance, regulatory, and tax-related services;
- costs related to compliance with the rules and regulations of the SEC and listing standards applicable to companies listed on a national securities exchange;
- director and officer insurance costs; and
- investor and public relations costs.

In addition, if we obtain regulatory approval for any of our product candidates and do not enter into a third-party commercialization collaboration, we expect to incur significant expenses related to building a sales and marketing team to support product sales, marketing, and distribution activities.

Non-operating Income (Expense)

Non-operating income (expense) consists primarily of interest income on our cash and cash equivalents and marketable securities, and non-cash changes in the fair value of our outstanding preferred stock warrant liability.

Results of Operations

Comparison of the Years Ended December 31, 2025 and 2024

The following table summarizes our results of operations for the years ended December 31, 2025 and 2024 (in thousands):

	Year Ended December 31,		
	2025	2024	Change
Operating expenses			
Research and development	$ 16,744	$ 51,171	$ (34,427)
General and administrative	13,660	13,659	1
Total operating loss	**(30,404)**	**(64,830)**	**(34,426)**
Non-operating income (expense)			
Interest income	3,920	1,721	2,199
Realized gain on sale of marketable securities, net	119	955	(836)
Gain (loss) on change in fair value of derivative instruments	1,161	(947)	2,108
Total non-operating income	**5,200**	**1,729**	**3,471**
Loss before income tax	**(25,204)**	**(63,101)**	**(37,897)**
Income tax provision	1	1	—
Net loss	**$ (25,205)**	**$ (63,102)**	**$ (37,897)**

Revenue

We generated no revenue during the year ended December 31, 2025 or 2024.

Research and Development Expenses

The following table summarizes our research and development expenses for the periods presented (in thousands):

	Year Ended December 31,		
	2025	2024	Change
Direct research and development expenses			
Clinical trial	$ 4,727	$ 42,369	$ (37,642)
Formulation and CMC	3,805	2,270	1,535
Preclinical	129	1,845	(1,716)
Indirect and unallocated expenses			
Personnel-related	5,367	3,689	1,678
Consulting and other	2,716	998	1,718
Total research and development expenses	**$ 16,744**	**$ 51,171**	**$ (34,427)**

Research and development expenses were $16.7 million for the year ended December 31, 2025, compared to $51.2 million for the year ended December 31, 2024. The decrease of $34.4 million was primarily due to: (i) a $37.6 million decrease in clinical trial expenses primarily related to our Phase 2 trial of LB-102 in patients with acute schizophrenia, the majority of which took place in 2024 and (ii) a $1.7 million decrease in preclinical expenses primarily related to preclinical studies performed in 2024 required to initiate a Phase 3 clinical trial in patients with acute schizophrenia, partially offset by (iii) a $1.7 million increase in personnel-related expenses due to an increase in headcount; (iv) a $1.7 million increase in consulting and other expenses primarily due to the engagement of industry experts, and (v) a $1.5 million increase in formulation and CMC expenses due to the scale-up and production of LB-102 to be used for clinical development.

General and Administrative Expenses

General and administrative expenses were $13.7 million for the years ended December 31, 2025 and 2024. Changes in general and administrative expenses include: (i) a $3.0 million decrease related to the write off of deferred offering costs in 2024; partially offset by (ii) a $0.7 million increase in stock-based compensation primarily related to the stock option grants and the repricing of stock options upon the closing of the IPO in 2025; (iii) a $0.8 million increase in legal costs primarily related to increased operations and public company compliance; (iv) a $0.8 million increase in public company costs including directors' and officers' insurance and public relations costs; (v) a $0.4 million increase in consulting expenses primarily related to public company readiness; and (vi) a $0.3 million increase in personnel-related costs primarily related to increased headcount.

Non-operating Income (Expense)

Non-operating income was $5.2 million for the year ended December 31, 2025, compared to $1.7 million for the year ended December 31, 2024. The increase of $3.5 million was primarily due to: (i) a $2.1 million increase in the gain (loss) on change in fair value of derivative instruments primarily related to the decrease in the fair value of common stock, resulting from a gain on the change in fair value on warrant liabilities of $1.2 million during 2025 and a $0.9 million loss on the change in fair value of derivative liabilities during 2024; (ii) a $2.2 million increase in interest income related to the increased investment in marketable securities, partially offset by (iii) a $0.8 million decrease in the realized gain on marketable securities primarily due to more sales of investments in marketable securities in 2024 as compared to 2025.

Liquidity and Capital Resources

As of December 31, 2025, we had $295.2 million of cash, cash equivalents and marketable securities. 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. Prior to our IPO, we funded our operations primarily by gross proceeds of $121.7 million from issuances of our redeemable convertible preferred stock, common stock and convertible notes. In September 2025, we completed our IPO pursuant to which we issued and sold an aggregate of 21,850,000 shares of common stock at a price

to the public of $15.00 per share. We received aggregate net proceeds of $302.3 million after deducting underwriting discounts and commissions of $22.9 million and other offering expenses of $2.5 million. In February 2026, we sold shares of our common stock pursuant to a securities purchase agreement in exchange for gross proceeds of approximately $100.0 million, before deducting any transaction-related expenses. Until required for use in our business, we typically invest our cash, in accordance with our investment policy, in money market funds and fixed income securities including U.S. treasury bills and government securities. We attempt to minimize credit risk related to our cash and cash equivalents and marketable securities by maintaining a well-diversified portfolio that limits the amount of exposure as to maturity and investment type.

Our primary use of cash has been to fund operating expenses, which consist of research and development and general and administrative expenditures. As we progress through the phases of development of LB-102 and any of our future product candidates, we anticipate that we will incur increasing losses in future quarters and years compared to historical periods.

Cash Flows

The following table sets forth a summary of the net cash flow activity for the years ended December 31, 2025 and 2024 (in thousands):

	Year Ended December 31,	
	2025	2024
Net cash used in operating activities	$ (35,208)	$ (53,052)
Net cash (used in) provided by investing activities	(39,887)	23,234
Net cash provided by financing activities	302,562	38,315
Net increase in cash, cash equivalents and restricted cash	$ 227,467	$ 8,497

Operating Activities

Cash used in operating activities for the year ended December 31, 2025 was $35.2 million, consisting of net loss of $25.2 million adjusted for non-cash items, including a $4.2 million charge for stock-based compensation expense, $0.3 million in amortization of premiums on investments, and $0.3 million of depreciation and amortization partially offset by change in the fair value of the warrant liabilities of $1.2 million. Additionally, we had outflows of $13.7 million due to a change in our net operating assets and liabilities from the year ended December 31, 2024, including a $12.3 million increase in prepaid expenses and other current assets primarily related to advance payments to our CRO for the clinical trials initiated in 2025, a $0.9 million decrease in accounts payable and accrued expense primarily related to timing of payments, and a $0.3 million increase in accrued interest on marketable securities primarily due to our holding of no marketable securities investments through September 2025.

Cash used in operating activities for the year ended December 31, 2024 was $53.1 million, consisting of net loss of $63.1 million adjusted for non-cash items, including the realized gain on marketable securities of $1.0 million, partially offset by non-cash items including: (i) stock-based compensation expense of $3.1 million; (ii) write off of deferred offering costs of $3.2 million, (iii) change in fair value of the warrant liabilities of $0.9 million; and (iv) lease expense of $0.3 million related to the lease agreement executed in May 2024. Additionally, we had inflows of $3.3 million due to a change in our net operating assets and liabilities from the year ended December 31, 2023, including a $5.0 million increase in accounts payable and accrued expense related to timing of payments, clinical trial expenses and compensation and termination expenses, partially offset by a $1.7 million increase in prepaid expenses primarily related to advance payments to our CRO for the Phase 2 acute schizophrenia trial.

Investing Activities

Cash used in investing activities for the year ended December 31, 2025 was $39.9 million primarily related to $44.8 million for the purchase of marketable securities to invest our excess cash, partially offset by $5.0 million in proceeds from sale and maturities of marketable securities.

Cash provided by investing activities for the year ended December 31, 2024 was $23.2 million primarily related to proceeds from sale and maturities of marketable securities, partially offset by the purchase of marketable securities to invest our excess cash.

Financing Activities

Cash provided by financing activities for the year ended December 31, 2025 was $302.6 million primarily related to the proceeds from the IPO, net of issuance costs.

Cash provided by financing activities for the year ended December 31, 2024 was $38.3 million primarily related to the proceeds from the issuance of redeemable convertible Series C preferred stock, net of issuance costs.

Future Funding Requirements

We expect our expenses to increase substantially in connection with our ongoing activities, in particular as we continue to advance LB-102 and any of our future product candidates through clinical trials, as well as additional costs associated with operating as a public company.

As of December 31, 2025, we had cash, cash equivalents and marketable securities of $295.2 million, which does not include net proceeds from our $100 million private placement in February 2026. Based on our current plans, we believe that our existing cash, cash equivalents and marketable securities, including net proceeds from our private placement in February 2026, will be sufficient to meet our anticipated operating and capital expenditure requirements into the second quarter of 2029.

We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with research, development, and commercialization of pharmaceutical product candidates, we are unable to estimate the exact amount of our working capital requirements. Our future funding requirements will depend on and could increase significantly as a result of many factors, including:

- the scope, progress, results, and costs of researching, developing and manufacturing LB-102 for our current and future indications, as well as other product candidates we may develop;
- the timing of, and the costs involved in, obtaining marketing approvals for LB-102 for our current and future indications, as well as future product candidates we may develop and pursue;
- the number of future indications and product candidates that we pursue and their development requirements;
- if approved, the costs of commercialization activities for LB-102 for the treatment of acute schizophrenia, bipolar depression, adjunctive MDD, or any other approved indication, or any other product candidate that receives regulatory approval to the extent such costs are not the responsibility of any future collaborators, including the costs and timing of establishing product sales, marketing, distribution, and manufacturing capabilities;
- subject to receipt of regulatory approval, revenue, if any, received from commercial sales of LB-102 for any program or revenues received from any future product candidates;
- the extent to which we in-license or acquire rights to other products, product candidates, or technologies;
- our headcount growth and associated costs as we expand our organization to achieve our objectives;
- the costs of preparing, filing, and prosecuting patent applications, and maintaining and protecting our intellectual property rights, including enforcing and defending intellectual property related claims; and
- the costs of operating as a public company.

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. Further, our operating plans may change in the future, and we may need additional funds to meet operational needs and capital requirements associated with such operating plans.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our operations through a combination of equity financings, debt financings, collaborations with other companies or other strategic transactions. We do not currently have any committed external source of funds. 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 common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making acquisitions or capital expenditures, or declaring dividends. If we raise additional funds through collaborations, strategic alliances, or marketing, distribution, or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs, or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay, limit, reduce, or terminate our research, product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Further, our operating plans may change, and we may need additional funds to meet operational needs and capital requirements for clinical trials and other research and development activities. We currently have no credit facility or committed sources of capital. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated product development programs.

Contractual Obligations and Commitments

Leases

In May 2024, we entered into a new lease agreement for office space in New York, New York totaling approximately 8,900 square feet. The term of this lease commenced on June 21, 2024, which is the date we took control over the leased premises. The lease term continues through March 2032. In November 2025, we entered into an amendment to the lease agreement providing for the lease of approximately 4,600 square feet of additional office space. The lease amendment term continues through March 2032. See Note 7 *Leases* to our audited financial statements for more information.

Funding Commitments

We enter into contracts in the normal course of business with CROs, CDMOs, and other third parties for clinical trials, preclinical research studies, and testing and manufacturing services. These contracts are cancelable by us upon prior written notice. Payments due upon cancellation consist primarily of payments for services provided or expenses incurred, including noncancelable obligations of our service providers, up to the date of cancellation. The amount and timing of such payments are not known. See Note 13 *Commitments and Contingencies* to our audited financial statements for more information.

Recently Issued Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position, results of operations, or cash flows is disclosed in Note 2 of our audited financial statements appearing elsewhere in this Annual Report on Form 10-K.

Critical Accounting Estimates

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

We define our critical accounting estimates as those that require us to make subjective estimates and judgments about matters that are uncertain and are likely to have a material impact on our financial condition and results of operations. While our significant accounting policies are more fully described in Note 2 to our audited financial statements appearing elsewhere in this Annual Report on Form 10-K, we believe the following are the critical accounting policies used in the preparation of our financial statements that require significant estimates and judgments.

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, including our site contracts for sites that are participating in our ongoing clinical trials, communicating with our personnel to identify services that have been performed on our behalf, and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. The majority of our service providers invoice us monthly in arrears for services performed or when contractual milestones are met. We make estimates of our accrued expenses as of each balance sheet date based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments if necessary.

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

Although we do not expect our estimates to be materially different from amounts incurred, if our estimates of the status and timing of services performed differ from the actual status and timing of services performed, it could result in us reporting amounts that are too high or too low in any particular period.

Costs incurred in obtaining technology licenses through asset acquisitions or in-licensing arrangements are charged to research and development expense if the acquired technology has not reached technological feasibility and has no alternative future use.

Stock-Based Compensation

We account for our stock-based compensation awards in accordance with the Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or ASC, Topic 718, Compensation—Stock Compensation, or ASC Topic 718. We have issued stock-based compensation awards including stock options and restricted stock awards and we also account for certain issuances of warrants in accordance with ASC Topic 718.

We measure the cost of employee, nonemployee, and director services received in exchange for an award of equity instruments based on the fair value of the award on the date of grant and recognize the related expense over the period during which the employee, nonemployee or director is required to provide service in exchange for the award on a straight line basis.

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

- Fair value of common stock.
- Expected term. The expected term represents the period that the stock-based awards are expected to be outstanding. The expected term for our stock options was calculated based on the weighted-average vesting term of the awards and the contract period, or simplified method.

- Expected volatility. Since we do not have sufficient trading history to estimate the volatility of our common stock, the expected volatility was estimated based on the average historical volatilities of common stock of comparable publicly traded entities over a period equal to the expected term of the stock option grants. The comparable companies were chosen based on their size, stage of their life cycle, or area of specialty. We will continue to apply this process until enough historical information regarding the volatility of our stock price becomes available.
- Risk-free interest rate. The risk-free interest rate is based on a treasury instrument whose term is consistent with the expected term of the stock options.
- Expected dividend yield. We have never paid dividends on our common stock and have no plans to pay dividends on our common stock. Therefore, we used an expected dividend yield of zero.

Changes in the foregoing assumptions can materially affect the fair value and ultimately how much stock-based compensation expense is recognized. These inputs are subjective and generally require significant analysis and judgment to develop.

Warrants

We review the terms of debt instruments, equity instruments, and other financing arrangements to determine whether there are embedded derivative features, including embedded conversion options that are required to be bifurcated and accounted for separately as a derivative financial instrument. Additionally, in connection with the issuance of financing instruments, we may issue freestanding warrants.

We account for warrants as either equity-classified or liability-classified instruments based on an assessment of the warrant's specific terms and applicable authoritative guidance in FASB ASC Topic 480, Distinguishing Liabilities from Equity, or ASC Topic 480, and FASB ASC Topic 815, Derivatives and Hedging, or ASC Topic 815. The assessment considers whether the warrants are freestanding financial instruments pursuant to ASC Topic 480, meet the definition of a liability pursuant to ASC Topic 480, and whether the warrants meet all of the requirements for equity classification under ASC Topic 815, including whether the warrants are indexed to our own stock and whether the warrant holders could potentially require "net cash settlement" in a circumstance outside of our control, among other conditions for equity classification. This assessment, which requires the use of professional judgment, is conducted at the time of warrant issuance and as of each subsequent quarterly period end date while the warrants are outstanding.

For warrants that meet all criteria for equity classification, the warrants are recorded as a component of additional paid-in capital, on the statement of stockholders' deficit at the time of issuance. For warrants that do not meet all the criteria for equity classification, the warrants are required to be recorded at their initial fair value on the date of issuance, and on each balance sheet date thereafter. Changes in the estimated fair value of the warrants are recognized as a non-cash gain or loss in other expense, net, on the statements of operations. The fair value of the warrants was estimated using the Black-Scholes option pricing model, which requires the use of highly subjective and unobservable assumptions to determine the fair value of the warrants, including the fair value of common stock, expected term, expected volatility, risk free interest rate and expected dividend yield.

Emerging Growth Company and Smaller Reporting Company Status

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

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 some accounting standards until those standards would otherwise apply to private companies. We have elected to take advantage of the benefits of this extended transition period, and therefore, we are not subject to the same requirements to adopt new or revised accounting standards as other public companies that are not emerging growth companies; however, we may adopt certain new or revised accounting standards early. We will remain an "emerging growth company" until the earliest to occur of: (i) the last day of the fiscal year in which we have $1.235 billion or more in annual revenue; (ii) the date on which we first qualify as a large accelerated filer under the rules of the SEC; (iii) the date on which we have, in any prior three-year period issued more than $1.0 billion in non-convertible debt securities; and (iv) the last day of the fiscal year following the fifth anniversary of the consummation of our IPO.

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.

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information required under this item.

Item 8. Financial Statements and Supplementary Data.

The financial statements listed in the Index to Financial Statements beginning on page F-1 are filed as part of this Annual Report on Form 10-K and incorporated by reference herein.

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 are responsible for maintaining disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Disclosure controls and procedures are controls and other procedures designed to ensure that the information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and our principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

Based on our management's evaluation (with the participation of our principal executive officer and our principal financial officer) of our disclosure controls and procedures as required by Rule 13a-15 under the Exchange Act and the material weaknesses previously identified and further discussed below, our principal executive officer and our principal financial officer have concluded that our disclosure controls and procedures were not effective at the reasonable level of assurance as of December 31, 2025.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as such term is defined in Exchange Act Rule 13a-15(f). Internal control over financial reporting is a process designed under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America.

As of December 31, 2025, our management assessed the effectiveness of our internal control over financial reporting using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control-Integrated Framework (2013 Framework).

Management identified material weaknesses in our internal control over financial reporting as of December 31, 2025 with respect to (i) an insufficient number of qualified resources to ensure adequate oversight and accountability over the performance of controls, including proper segregation of duties; controls over the completeness and accuracy of information used in the operation of control activities across substantially all financial statement areas; and retention of control evidence, and (ii) improper access and a lack of review over user access and user provisioning as it relates to our information technology environment and general controls over information systems that support the financial reporting process. These material weaknesses could result in a misstatement of substantially all of our accounts or disclosures that would result in a material misstatement of our annual or interim financial statements that would not be prevented or detected.

Based on this assessment, our management concluded that, as of December 31, 2025, our internal control over financial reporting was not effective based on those criteria.

This annual report does not include an attestation report of our registered public accounting firm due to the Securities and Exchange Commission adopted amendments to the accelerated filer and large accelerated filer definitions on March 12, 2020. Following the adoption of the amendments, smaller reporting companies with less than $100 million in revenues will continue to be required to establish and maintain effective internal control over financial reporting, or ICFR, but will no longer be required to obtain a separate attestation of their ICFR from an outside auditor.

Remediation Plan for the Material Weaknesses

To remediate the deficiencies described above and prevent similar deficiencies in the future, we will continue to increase the number of resources (internal or third-party) dedicated to our accounting and finance team, including personnel with additional knowledge, experience, and training, to ensure we have adequate staff, to segregate key duties, and to comply with company policies and procedures. We have engaged a third-party provider to assist in designing and implementing internal control activities, including over information technology.

Although we have begun the implementation of these remediation efforts, the material weaknesses will not be considered fully remediated until the applicable remedial controls operate for a sufficient period of time and management has concluded, through testing, that these controls are operating effectively. Any actions we have taken or may take to remediate these deficiencies are subject to continued management review supported by testing, as well as oversight by the Audit Committee of our board of directors.

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

Changes in Internal Control over Financial Reporting

There were no other changes to our internal control over financial reporting that occurred during the quarter ended December 31, 2025 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

During the three months ended December 31, 2025, none of our directors or officers adopted or terminated any "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as those terms are defined in Item 408 of Regulation S-K.

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

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this item (other than the information set forth in the next paragraph in this Item 10) will be included in our definitive proxy statement with respect to our 2026 Annual Meeting of Shareholders to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2025 and is incorporated herein by reference.

We have adopted a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer, or persons performing similar functions, and third-party consultants. We have posted a current copy of the code on our website, www.lbpharma.us. In addition, we intend to post on our website all disclosures that are required by law or the Nasdaq listing standards concerning any amendments to, or waivers from, any provision of the code. The reference to our website does not constitute incorporation by reference of the information contained at or available through our website.

We have adopted insider trading policies and procedures governing the purchase, sale, and/or other dispositions of our securities by directors, officers and employees. In addition, it is our intent to comply with the applicable laws and regulations relating to insider trading.

Item 11. Executive Compensation.

The information required by this item will be included in our definitive Proxy Statement to be filed with the SEC in connection with our 2026 Annual Meeting of Stockholders within 120 days after the end of the fiscal year ended December 31, 2025 and is incorporated herein by reference.

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

The information required by this item will included in our definitive Proxy Statement to be filed with the SEC in connection with our 2026 Annual Meeting of Stockholders within 120 days after the end of the fiscal year ended December 31, 2025 and is incorporated herein by reference.

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

The information required by this item will be included in our definitive Proxy Statement to be filed with the SEC in connection with our 2026 Annual Meeting of Stockholders within 120 days after the end of the fiscal year ended December 31, 2025 and is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services.

The information required by this item will be included in our definitive Proxy Statement to be filed with the SEC in connection with our 2026 Annual Meeting of Stockholders within 120 days after the end of the fiscal year ended December 31, 2025 and is incorporated herein by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

The following documents are filed as part of this Annual Report on Form 10-K:

(a) Financial Statements. See Index to Financial Statements included in the financial statements in this Annual Report on Form 10-K.

(b) Financial Statement Schedules. All financial statement schedules are omitted because they are not applicable or required, or the information required to be set forth therein is included in the financial statements or notes thereto included in the Index to Financial Statements of this Annual Report on Form 10-K.

(c) Exhibits. The exhibits required to be filed as part of this Annual Report on Form 10-K are listed in the Exhibit List attached hereto and are incorporated herein by reference.

Exhibit Index

Exhibit Number	Description	Form	File No.	Exhibit	Filing Date	Filed Herewith
3.1	Amended and Restated Certificate of Incorporation of the Registrant.	8-K	001-42831	3.1	September 12, 2025	
3.2	Amended and Restated Bylaws of the Registrant.	S-1	333-289812	3.4	August 22, 2025	
4.1	Description of Registrant's Securities					X
4.2	Form of Common Stock Certificate.	S-1/A	333-289812	4.1	September 8, 2025	
4.3	Investors' Rights Agreement, by and among the Registrant and certain of its stockholders, dated as of August 29, 2023.	S-1	333-289812	4.2	August 22, 2025	
4.4	Form of Class A Warrants	S-1	333-289812	4.3	August 22, 2025	
4.5	Form of Class B Warrants	S-1	333-289812	4.4	August 22, 2025	
4.6	Form of Maxim Warrants	S-1	333-289812	4.5	August 22, 2025	
4.7	Form of New Series B Warrants	S-1	333-289812	4.6	August 22, 2025	
4.8	Form of Series B-1 Warrants	S-1	333-289812	4.7	August 22, 2025	
4.9	Form of Pre-Funded Warrant	8-K	001-42831	4.1	February 5, 2026	
10.1	2017 Equity Incentive Plan	S-1	333-289812	10.1	August 22, 2025	
10.2	Form of Option Grant Notice and Agreement, Exercise Notice, and Restricted Award Notice under the 2017 Equity Incentive Plan	S-1	333-289812	10.2	August 22, 2025	
10.3	2018 Equity Incentive Plan	S-1	333-289812	10.3	August 22, 2025	
10.4	Form of Option Grant Notice and Agreement, Exercise Notice, and Restricted Award Notice under the 2018 Equity Incentive Plan	S-1	333-289812	10.4	August 22, 2025	
10.5	2023 Equity Incentive Plan	S-1	333-289812	10.5	August 22, 2025	
10.6	Amendment No. 1 to 2023 Equity Incentive Plan	S-1	333-289812	10.6	August 22, 2025	
10.7	Form of Option Grant Notice and Agreement, Exercise Notice, and Restricted Award Notice under the 2023 Equity Incentive Plan	S-1	333-289812	10.7	August 22, 2025	
10.8	2025 Equity Incentive Plan	S-1/A	333-289812	10.8	September 8, 2025	
10.9	Form of Option Grant Notice and Agreement, and Exercise Notice under the 2025 Equity Incentive Plan	S-1/A	333-289812	10.9	September 8, 2025	
10.10	Form of RSU Award Grant Notice and Agreement under the 2025 Equity Incentive Plan	S-1/A	333-289812	10.10	September 8, 2025	
10.11	2025 Employee Stock Purchase Plan	S-1/A	333-289812	10.11	September 8, 2025	
10.12	Form of Indemnification Agreement between the Registrant and each of its directors and executive officers	S-1	333-289812	10.12	August 22, 2025	
10.13	Executive Employment Agreement, dated November 1, 2024, between Heather Turner and the Registrant	S-1	333-289812	10.13	August 22, 2025	
10.14	Executive Employment Agreement, dated February 3, 2025, between Gad Soffer and the Registrant	S-1	333-289812	10.14	August 22, 2025	
10.15	Amended and Restated Executive Employment Agreement, dated September 4, 2025, between Anna Eramo and the Registrant	S-1/A	333-289812	10.15	September 8, 2025	

10.16	Amended and Restated Executive Employment Agreement, dated September 3, 2025, between Marc Panoff and the Registrant	S-1/A	333-289812	10.16	September 8, 2025	
10.17	Executive Employment Agreement, dated February 3, 2025, between Richard Silva and the Registrant	S-1	333-289812	10.18	August 22, 2025	
10.18	Transition, Consulting, and Separation Agreement, dated November 26, 2024, between Zachary Prensky and the Registrant	S-1	333-289812	10.21	August 22, 2025	
10.19	Amendment No. 1 to Transition, Consulting, and Separation Agreement between Zachary Prensky and the Registrant					X
10.20	Executive Employment Agreement, dated June 12, 2024, between Roger Sawhney and the Registrant	S-1	333-289812	10.22	August 22, 2025	
10.21	Separation Agreement, dated May 6, 2025, between Roger Sawhney and the Registrant	S-1	333-289812	10.23	August 22, 2025	
10.22	Executive Employment Agreement, dated October 28, 2025, between Kaya Pai Panandiker and the Registrant					X
10.23	Non-Employee Director Compensation Policy	S-1/A	333-289812	10.23	September 8, 2025	
10.24	Form of Amended and Restated Royalty Participation Agreement by and between the Registrant and certain holders	S-1	333-289812	10.25	August 22, 2025	
10.25	Lease Agreement, dated May 20, 2024, between the Registrant and One Penn Plaza LLC	S-1	333-289812	10.26	August 22, 2025	
10.26	First Amendment to Lease Agreement, dated as of November 10, 2025, by and between the Registrant and One Penn Plaza LLC	8-K	001-42831	10.1	November 13, 2025	
10.27	Form of Securities Purchase Agreement	8-K	001-42831	10.1	February 5, 2026	
10.28	Form of Registration Rights Agreement	8-K	001-42831	10.2	February 5, 2026	
19.1	Insider Trading Policy					X
21.1	List of Subsidiaries	S-1	333-289812	21.1	August 22, 2025	
23.1	Consent of BDO USA, P.C., Independent Registered Public Accounting Firm					X
24.1	Power of Attorney (see signature page)					X
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 Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
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 Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
32.1*	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X
97.1	Incentive Compensation Recoupment Policy					X
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 With Embedded Linkbase Documents					
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)					

* These certifications are being furnished solely to accompany this annual report pursuant to 18 U.S.C. Section 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934 and are not to be incorporated by reference into any filing of the registrant, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

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**.**

LB Pharmaceuticals Inc

Date: March 26, 2026 By: /s/ Heather Turner
Heather Turner
Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Heather Turner and Marc Panoff, and each of them, as his true and lawful attorney-in-fact and agent with full power of substitution and resubstitution, for such individual in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully for all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them, or the individual's substitute, may lawfully do or cause to be done by virtue hereof.

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

Name	Title	Date
/s/ Heather Turner Heather Turner	Chief Executive Officer and Director (Principal Executive Officer)	March 26, 2026
/s/ Marc Panoff Marc Panoff	Senior Vice President of Finance (Principal Financial and Accounting Officer)	March 26, 2026
/s/ Scott Garland Scott Garland	Chairman of the Board and Director	March 26, 2026
/s/ Rekha Hemrajani Rekha Hemrajani	Director	March 26, 2026
/s/ William Kane William Kane	Director	March 26, 2026
/s/ Robert Lenz Robert Lenz	Director	March 26, 2026
/s/ Rebecca Luse Rebecca Luse	Director	March 26, 2026
/s/ Ran Nussbaum Ran Nussbaum	Director	March 26, 2026
/s/ Zachary Prensky Zachary Prensky	Director	March 26, 2026
/s/ Robert R. Ruffolo, Jr. Robert R. Ruffolo Jr.	Director	March 26, 2026

INDEX TO FINANCIAL STATEMENTS

Financial Statements

Report of Independent Registered Public Accounting Firm

Stockholders and Board of Directors
LB Pharmaceuticals Inc
New York, New York

Opinion on the Financial Statements

We have audited the accompanying balance sheets of LB Pharmaceuticals Inc (the "Company") as of December 31, 2025 and 2024, the related statements of operations, comprehensive loss, redeemable convertible preferred stock and stockholders' equity (deficit), and cash flows for each of the years then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2025 and 2024, and the results of its operations and its cash flows for each of the years then ended**,** in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our 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. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

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

/s/ BDO USA, P.C.

We have served as the Company's auditor since 2016.

New York, New York
March 26, 2026

LB Pharmaceuticals Inc
Balance Sheets
(in thousands, except share and per share data)

	As of December 31,	
	2025	**2024**
Assets		
Current assets		
Cash and cash equivalents	$ 250,173	$ 22,978
Marketable securities	45,040	5,021
Prepaid expenses and other current assets	13,219	880
Total current assets	**308,432**	**28,879**
Operating lease right-of-use assets, net	2,151	2,298
Property and equipment, net	1,581	1,859
Restricted cash	770	498
Total assets	**$ 312,934**	**$ 33,534**
Liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)		
Current liabilities		
Accounts payable	$ 2,127	$ 2,320
Accrued expenses	4,585	5,302
Operating lease liability, current	730	487
Total current liabilities	**7,442**	**8,109**
Derivative liability - warrants	1,343	2,504
Operating lease liability, noncurrent	2,839	3,216
Total liabilities	**11,624**	**13,829**
Commitments and contingencies (Note 13)		
Redeemable convertible preferred stock [1]		
Series Seed preferred stock, $0.0001 par value, zero and 295,467 shares authorized, zero and 295,467 shares issued and outstanding as of December 31, 2025 and 2024. Liquidation preference of zero and $443 as of December 31, 2025 and 2024, respectively.	—	435
Series A preferred stock, $0.0001 par value, zero and 3,655,374 shares authorized, zero and 3,655,374 shares outstanding as of December 31, 2025 and 2024, respectively. Liquidation preference of zero and $8,407 as of December 31, 2025 and 2024, respectively.	—	6,179
Series B preferred stock, $0.0001 par value, zero and 301,119 authorized, zero and 301,119 shares issued and outstanding as of December 31, 2025 and 2024, respectively. Liquidation preference of zero and $903 as of December 31, 2025 and 2024, respectively.	—	580
Series C preferred stock, $0.0001 par value, zero and 75,000,000 shares authorized, zero and 73,820,346 shares issued and outstanding as of December 31, 2025 and December 31, 2024, respectively. Liquidation preference of zero and $110,731 as of December 31, 2025 and December 31, 2024, respectively.	—	107,065
Stockholders' equity (deficit)		
Common stock, $0.0001 par value, 500,000,000 and 105,000,000 shares authorized, 25,299,372 and 251,655 shares issued and outstanding as of December 31, 2025 and 2024, respectively.	3	1
Additional paid-in capital	430,667	9,657
Accumulated deficit	(129,528)	(104,323)
Accumulated other comprehensive income	168	111
Total stockholders' equity (deficit)	**$ 301,310**	**$ (94,554)**
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	**$ 312,934**	**$ 33,534**

[1] Shares authorized, shares issued and outstanding are not adjusted for the reverse stock split detailed in Note 1 *Business Overview*.

See accompanying notes to financial statements.

LB Pharmaceuticals Inc
Statements of Operations
(in thousands, except share and per share data)

	Year Ended December 31,	
	2025	**2024**
Operating expenses		
Research and development	$ 16,744	$ 51,171
General and administrative	13,660	13,659
Total operating loss	**(30,404)**	**(64,830)**
Non-operating income		
Interest income	3,920	1,721
Realized gain on sale of marketable securities, net	119	955
Gain (loss) on change in fair value of derivative instruments	1,161	(947)
Total non-operating income	**5,200**	**1,729**
Loss before income tax	**(25,204)**	**(63,101)**
Income tax provision	1	1
Net loss	**$ (25,205)**	**$ (63,102)**
Net loss per share, basic and diluted	$ (3.13)	$ (176.15)
Weighted average shares outstanding used in calculating net loss per share, basic and diluted	8,045,145	358,229

See accompanying notes to financial statements.

LB Pharmaceuticals Inc
Statements of Comprehensive Loss
(in thousands)

	Year Ended December 31,	
	2025	**2024**
Net loss	$ (25,205)	$ (63,102)
Unrealized gain (loss) on marketable securities, net	57	(163)
Comprehensive loss	**$ (25,148)**	**$ (63,265)**

See accompanying notes to financial statements.

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

	Redeemable Convertible Preferred Stock													
	Series Seed		Series A		Series B		Series C		Common Stock		Additional Paid-in	Accumulated	Accumulated Other Comprehensive	Total Stockholders'
	Shares [1]	Amount	Shares [1]	Amount	Shares [1]	Amount	Shares [1]	Amount	Shares	Amount	Capital	Deficit	Income	Deficit
Balance, December 31, 2023	**295,467**	**$ 435**	**3,655,374**	**$ 6,179**	**301,119**	**$ 580**	**47,153,680**	**$ 68,773**	**249,476**	**$ 1**	**$ 6,473**	**$ (41,221)**	**$ 274**	**$ (34,473)**
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	3,090	—	—	3,090
Unrealized loss on marketable securities	—	—	—	—	—	—	—	—	—	—	—	—	(163)	(163)
Issuance of redeemable convertible series C preferred stock, net of issuance costs	—	—	—	—	—	—	26,666,666	38,292	—	—	—	—	—	—
Shares issued upon exercise of warrants	—	—	—	—	—	—	—	—	253	—	3	—	—	3
Shares issued upon exercise of options	—	—	—	—	—	—	—	—	493	—	20	—	—	20
Issuance of common stock for services	—	—	—	—	—	—	—	—	1,433	—	71	—	—	71
Net loss	—	—	—	—	—	—	—	—	—	—	—	(63,102)	—	(63,102)
Balance, December 31, 2024	**295,467**	**$ 435**	**3,655,374**	**$ 6,179**	**301,119**	**$ 580**	**73,820,346**	**$ 107,065**	**251,655**	**$ 1**	**$ 9,657**	**$ (104,323)**	**$ 111**	**$ (94,554)**
Conversion of preferred stock to common stock	(295,467)	(435)	(3,655,374)	(6,179)	(301,119)	(580)	(73,820,346)	(107,065)	3,191,334	—	114,259	—	—	114,259
Issuance of common stock upon initial public offering, net of issuance costs	—	—	—	—	—	—	—	—	21,850,000	2	302,313	—	—	302,315
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	4,191	—	—	4,191
Unrealized gain on marketable securities	—	—	—	—	—	—	—	—	—	—	—	—	57	57
Shares issued upon exercise of options and warrants	—	—	—	—	—	—	—	—	6,383	—	247	—	—	247
Net loss	—	—	—	—	—	—	—	—	—	—	—	(25,205)	—	(25,205)
Balance, December 31, 2025	**—**	**$ —**	**—**	**$ —**	**—**	**$ —**	**—**	**$ —**	**25,299,372**	**$ 3**	**$ 430,667**	**$ (129,528)**	**$ 168**	**$ 301,310**

(1) Shares for the redeemable convertible preferred stock are not adjusted for the reverse stock split detailed in Note 1 *Business Overview*.

See accompanying notes to financial statements.

LB Pharmaceuticals Inc
Statements of Cash Flows
(in thousands)

	Year Ended December 31,	
	2025	**2024**
Operating activities		
Net loss	$ (25,205)	$ (63,102)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	4,191	3,090
Shares issued for services rendered	—	71
Loss on write off of property and equipment	8	—
Write off of deferred offering costs	—	3,219
Depreciation and amortization	321	91
Noncash lease expense	147	308
Realized gain on marketable securities, net	(119)	(955)
Amortization (accretion) of premiums (discounts) on investments, net	261	(34)
(Gain) loss on change in fair value of derivative instruments	(1,161)	947
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(12,339)	(1,757)
Operating lease liability	(134)	(60)
Accrued interest on marketable securities	(268)	114
Accounts payable and accrued expenses	(910)	5,016
Net cash used in operating activities	**(35,208)**	**(53,052)**
Investing activities		
Purchases of property and equipment	(52)	(769)
Purchase of marketable securities	(44,836)	(29,746)
Proceeds from the sale of marketable securities	2,501	23,649
Maturities of marketable securities	2,500	30,100
Net cash (used in) provided by investing activities	**(39,887)**	**23,234**
Financing activities		
Proceeds from initial public offering	327,750	—
Payment of issuance costs for initial public offering	(25,435)	—
Proceeds from exercise of warrants and options	247	23
Proceeds from issuance of redeemable convertible Series C preferred stock	—	40,000
Payment of issuance costs of redeemable convertible Series C preferred stock	—	(1,708)
Net cash provided by financing activities	**302,562**	**38,315**
Net increase in cash, cash equivalents and restricted cash	**227,467**	**8,497**
Cash, cash equivalents and restricted cash, beginning of year	**23,476**	**14,979**
Cash, cash equivalents and restricted cash, end of year	**$ 250,943**	**$ 23,476**
Supplemental disclosures of cash flow information		
Income tax paid	$ 1	$ 1
Supplemental disclosures of noncash investing and financing information		
Conversion of 78,072,306 shares [(1)] of redeemable convertible preferred stock to common stock upon the closing of initial public offering	$ 114,260	$ —
Right of use assets in exchange for operating lease liabilities	$ —	$ 2,405
Acquisition of leasehold improvements	$ —	$ 1,158

[(1)] Shares for the redeemable convertible preferred stock are not adjusted for the reverse stock split detailed in Note 1 *Business Overview*.

See accompanying notes to financial statements.

1. Business Overview

LB Pharmaceuticals Inc (the "Company" or "LB") was incorporated under the laws of the State of Delaware in September 2015 and is headquartered in New York, New York.

The Company is a late-stage biopharmaceutical company developing novel therapies for the treatment of a wide range of neuropsychiatric disorders including schizophrenia, bipolar depression, adjunctive treatment of major depressive disorder and other diseases. The Company is building a pipeline that leverages the broad therapeutic potential of the Company's lead product candidate, LB-102, which the Company believes has the potential to be the first benzamide antipsychotic drug approved for neuropsychiatric disorders in the United States. LB-102 is currently in late-stage clinical development for schizophrenia and bipolar depression. The Company is also planning to conduct a Phase 2 clinical trial evaluating LB-102 as an adjunctive treatment in major depressive disorder, or MDD.

Since the Company's inception, it has focused substantially all of its efforts and financial resources on organizing and staffing the Company, raising capital, building its intellectual property portfolio, undertaking preclinical studies and clinical trials and providing general and administrative support for these activities. The Company has not generated any product revenue related to its primary business purpose to date and is subject to a number of risks similar to those of other early stage companies, including dependence on key individuals, regulatory approval of product candidates, uncertainty of market acceptance of products, if approved, competition from substitute products and larger companies, compliance with government regulations, protection of proprietary technology, dependence on third parties, product liability and the need to obtain adequate additional financing to fund the development of its product candidates.

Initial Public Offering

On September 10, 2025, the Company's Registration Statement on Form S-1 (File No. 333-289812) for its initial public offering (the "IPO") was declared effective, and on September 12, 2025, the Company closed the IPO and issued 21,850,000 shares of common stock at a price to the public of $15.00 per share, including 2,850,000 shares issued upon the exercise in full of the underwriters' over-allotment option to purchase additional shares. The Company received gross proceeds of $327.8 million. Net proceeds were $302.3 million, after deducting underwriting commissions and other offering costs totaling $25.4 million. Immediately prior to the IPO closing, all of the outstanding shares of the Company's redeemable convertible preferred stock automatically converted into an aggregate of 3,191,334 shares of the Company's common stock, including 391,986 additional shares issuable upon conversion of Series C preferred stock due to certain anti-dilution adjustments.

Reverse Stock Split

On September 8, 2025, the Company effected a 1-for-27.8874 reverse stock split of the shares of common stock (the "Reverse Stock Split"). The number of authorized shares and par value per share were not adjusted as a result of the Reverse Stock Split. No fractional shares were issued; stockholders entitled to a fractional share received a cash payment in lieu thereof. All references to shares, equity awards and options (including exercise prices), share data, per share data, and related information contained in the financial statements have been retrospectively adjusted to reflect the effect of the Reverse Stock Split for all periods presented.

Emerging Growth Company and Smaller Reporting Company Status

The Company is an "emerging growth company" as defined in the JOBS Act and may remain an emerging growth company for up to five years following the completion of its IPO. For so long as the Company remains an emerging growth company, it is permitted to and intends to rely on certain exemptions from various public company reporting requirements, including not being required to have its internal control over financial reporting audited by its independent registered public accounting firm pursuant to Section 404(b) of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in its periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and any golden parachute payments not previously approved. Accordingly, the information contained herein may be different than the information received from other public companies.

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 some accounting standards until those standards would otherwise apply to private companies. The Company has elected to take advantage of the benefits of this extended transition period, and therefore, is not subject to the same requirements to adopt new or revised accounting standards as other public companies that are not emerging growth companies; however, the Company may adopt certain new or revised accounting standards early. The Company will remain an "emerging growth company" until the earliest to occur of: (i) the last day of the fiscal year in which the Company has $1.235 billion or more in annual revenue; (ii) the date on which the Company first qualifies as a large accelerated filer under the rules of the SEC; (iii) the date on which the Company has, in any prior three-year period, issued more than $1.0 billion in non-convertible debt securities; and (iv) the last day of the fiscal year following the fifth anniversary of the consummation of the Company's IPO.

The Company is also a "smaller reporting company" as defined in the Exchange Act. The Company may continue to be a smaller reporting company even after it is no longer an emerging growth company. The Company 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 the voting and non-voting common stock held by non-affiliates is less than $250.0 million measured on the last business day of the Company's second fiscal quarter, or the Company's annual revenue is less than $100.0 million during the most recently completed fiscal year and the voting and non-voting common stock held by non-affiliates is less than $700.0 million measured on the last business day of the Company's second fiscal quarter.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (“GAAP”).

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure at the date of the financial statements and the reported amounts of expenses during the reporting period. Significant estimates and assumptions reflected in these financial statements include, but are not limited to, the accrual of research and development costs and the valuation of common stock (prior to the Company's IPO), derivative warrant and stock-based compensation. Changes in estimates and assumptions are reflected in reported results in the period in which they become known. Estimates are periodically reviewed in light of changes in circumstances, facts and experience. Actual results could differ from the Company’s estimates.

Liquidity and Capital Resources

As of December 31, 2025, the Company had approximately $295.2 million of cash, cash equivalents and marketable securities and working capital of approximately $301.0 million. As of December 31, 2025, the Company had an accumulated deficit of $129.5 million. During the year ended December 31, 2025, the Company incurred a net loss of $25.2 million and negative cash flows from operations of $35.2 million. The Company has incurred net losses and negative cash flows from operations since its inception and anticipates it will continue to incur net losses for the foreseeable future.

Prior to the IPO, the Company funded its operations primarily through proceeds from issuances of redeemable convertible preferred stock, common stock and convertible notes. In September 2025, the Company completed its IPO as detailed above. The Company believes that its current capital resources, which consist of cash, cash equivalents and marketable securities, will be sufficient to fund operations through at least the next twelve months from the date the accompanying financial statements are issued based on its expected cash needs. As the Company continues to pursue its business plan, it expects to finance its operations through equity offerings, debt financings, or other capital sources, including current or potential future collaborations, licenses, and other similar arrangements. However, there can be no assurance that any additional financing or strategic arrangements will be available to the Company on acceptable terms, if at all.

Concentration of Risk

Financial instruments that potentially subject the Company to concentration of credit risk consist primarily of cash and cash equivalents and marketable securities. To minimize the risks related to cash, cash equivalents and marketable securities, the Company has established guidelines related to credit ratings and maturities intended to safeguard principal balances and maintain liquidity. The Company's investment portfolio is maintained in accordance with the Company's investment policy which defines allowable investments, specifies credit quality standards and limits the credit exposure of any single issuer.

The Company relies on third party vendors, including contract research organizations, to conduct and support its research and development activities. A significant disruption in the services provided by these vendors could delay the Company's clinical development timelines and adversely affect its research and development programs.

As of both December 31, 2025, and 2024, one research and development vendor individually represented more than 10% of the Company's accounts payable and accrued expenses. This vendor represented approximately 37% and 36% of accounts payable and accrued expenses as of December 31, 2025, and 2024, respectively.

Segment Information

The Company operates as a single reportable segment in the development of novel therapies for the treatment of neuropsychiatric diseases, including schizophrenia. The Company has not generated revenues since inception. The Company's chief operating decision maker ("CODM") is its Chief Executive Officer ("CEO"). The CODM reviews the Company's performance on an aggregate basis, thus the segment's loss is the Company's net loss, as reported on accompanying statements of operations, and the segment's assets are the Company's total assets, as reported on the accompanying balance sheets. Significant expenses provided to the CODM include research and development and general and administrative expenses, as reported on the accompanying statements of operations.

The following table presents the significant segment expenses regularly provided to the CODM and a reconciliation to net loss (in thousands):

	Year Ended December 31,	
	2025	**2024**
General and administrative expenses	**$ 13,660**	**$ 13,659**
Research and development expenses		
Clinical trial	4,727	42,369
Formulation and CMC	3,805	2,270
Preclinical	129	1,845
Total direct research and development expenses	**8,661**	**46,484**
Personnel-related	5,367	3,689
Consulting and other	2,716	998
Total indirect and unallocated research and development expenses	**8,083**	4,687
Total research and development expenses	**16,744**	**51,171**
Total operating loss	**(30,404)**	**(64,830)**
Non-operating income	5,200	1,729
Income tax provision	1	1
Net Loss	**$ (25,205)**	**$ (63,102)**

The CODM uses the information primarily to evaluate the Company's performance and allocate resources. This includes reviewing key financial metrics such as budget versus actual expenditures and assessing overall cash flow and liquidity to ensure the continuity of operations. This approach allows the CODM to monitor the Company's performance and make strategic adjustments as needed to support its operational and financial goals.

The Company's operations and all long-lived assets are located in the United States.

Cash and Cash Equivalents

The Company considers all highly liquid investments with original maturities of three months or less to be cash equivalents. The Company's cash and cash equivalents primarily consist of balances held at one financial institution and in money market funds. Cash balances may, at times, exceed the Federal Deposit Insurance Corporation ("FDIC") amounts. Management periodically assesses the financial condition of the banking institution and believes that any potential credit loss is minimal. As of December 31, 2025 and 2024, the Company's cash balance exceeded the FDIC insured limit of $250,000.

Restricted Cash

Restricted cash primarily consists of certificates of deposit that are held as collateral against the letter of credit that the Company is required to maintain for its operating lease agreement.

Marketable Securities

The Company accounts for marketable securities held as "available-for-sale" in accordance with Accounting Standards Codification ("ASC") 320, *Investments-Debt Securities.* The Company classifies these investments as current assets and carries them at fair value. Unrealized gains and losses are recorded as a separate component of stockholders' deficit as accumulated other comprehensive income. Realized gains or losses on marketable security transactions are reported in the statements of operations. The cost of securities sold is determined on a specific identification basis. Marketable securities are maintained at one financial institution and are governed by the Company's investment policy, as approved by the Company's board of directors.

The Company evaluates its marketable securities with unrealized loss positions for impairment by assessing if they are related to deterioration in credit risk and whether the entire amortized cost basis of the security will be recovered, the intent to sell, and whether it is more likely than not that the Company will be required to sell the securities before the recovery of their cost basis. Credit-related impairment losses, not to exceed the amount that fair value is less than the amortized cost basis, are recognized through an allowance for credit losses with changes in the allowance for credit losses recorded in the statements of operations.

No impairment losses related to marketable securities have been recognized during the years ended December 31, 2025 and 2024. Any unrealized losses on available-for-sale debt securities that are attributed to credit risk are recorded to earnings through an allowance for credit losses. Unrealized gains (losses) on available-for-sale debt securities were not material as of December 31, 2025 and 2024, and no allowance for credit losses was recorded.

Property and Equipment

Property and equipment are recorded at cost less accumulated depreciation. Depreciation and amortization expense is recognized using the straight-line method over the following estimated useful lives:

Asset Category	Estimated Useful Life
Leasehold improvements	Shorter of estimated useful life or remaining lease term
Computer equipment	3 years
Office furniture	5 years

Impairment of Long-Lived Assets

Long-lived assets consist of property and equipment as well as right-of-use assets. Long-lived assets to be held and used are tested for recoverability whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. If the sum of the estimated future undiscounted cash flows expected to result from the use and eventual disposition of an asset is less than the carrying amount of the asset, an impairment loss is

recognized. Measurement of an impairment loss is based on the fair value of the asset. The Company has not recorded any impairment losses on long-lived assets during the years ended December 31, 2025 and 2024.

Leases

According to ASC 842 *Leases*, the Company determines if an arrangement is or contains a lease at inception by assessing whether the arrangement contains an identified asset and whether it has the right to control the use of the identified asset over the term of the arrangement.

Right-of-use ("ROU") assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. Lease liabilities are recognized at the lease commencement date based on the present value of future lease payments over the lease term. The interest rate implicit in lease contracts is typically not readily determinable. To the extent that the Company is unable to utilize an interest rate implicit in the lease, the collateralized incremental borrowing rate is used based on the information available at the lease commencement date, in determining the present value of lease payments. ROU assets are based on the measurement of the lease liability and includes any lease payments made prior to or on lease commencement and initial direct costs incurred and excludes lease incentives, as applicable.

The Company has elected not to recognize leases with an original term of one year or less on the balance sheet.

The Company has elected to account for lease and non-lease components together as a single lease component for all underlying assets.

The Company typically only includes an initial lease term in its assessment of a lease arrangement. Options to renew a lease are not included in the Company's assessment unless there is reasonable certainty that the Company will renew. Assumptions made by the Company at the commencement date are re-evaluated upon occurrence of certain events, including a lease modification. A lease modification results in a separate contract when the modification grants the lessee an additional right of use not included in the original lease and when lease payments increase commensurate with the standalone price for the additional right of use. When a lease modification results in a separate contract, it is accounted for in the same manner as a new lease. If a lease modification is not accounted for as a separate contract, the Company reassesses lease classification as of the effective date of the modification (the date the modification is approved by both the Company and the lessor). The Company reallocates the remaining consideration in the contract and remeasures the lease liability using a discount rate determined at the effective date of the modification, as applicable.

Fair Value Measurements

The Company applies the fair value method under ASC 820 *Fair Value Measurements and Disclosure* to all financial assets and liabilities and nonfinancial assets and liabilities that are recognized or disclosed at fair value in the financial statements on a recurring basis. Fair value is defined as the exchange price that would be received for an asset or an exit price that would be paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. ASC 820 establishes a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to measurements involving significant unobservable inputs (Level 3 measurements). The three levels of the fair value hierarchy are as follows:

Level 1 – Observable inputs, such as quoted prices for identical assets and liabilities in active markets.

Level 2 – Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.

Level 3 – Unobservable inputs supported by little or no market data and requires management to develop its own assumptions based on best estimates of what market participants would use in pricing an asset or liability at the reporting date.

The level in the fair value hierarchy within which a fair value measurement in its entirety falls is based on the lowest-level input that is significant to the fair value measurement in its entirety. To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value may require significant judgment and involve uncertainty. Changes in fair value measurements could have a significant impact on the results of operations in any given period.

The carrying amounts of cash equivalents, marketable securities, accounts payable and accrued expenses approximate the related fair values due to the short-term maturities of these instruments. The Company's derivative liabilities are carried at fair value based on the fair value hierarchy. The Company invests its excess cash in financial instruments, which are readily convertible into cash, such as money market funds and government securities. Cash equivalents, where applicable, are classified as Level 1 or Level 2, as defined by the fair value hierarchy.

Stock-Based Compensation

The Company uses equity-based compensation programs to provide long-term performance incentives for its employees, directors and consultants. These incentives consist primarily of stock options and restricted stock grants.

The Company measures all stock options and other stock-based awards to employees, directors and non-employees based on the fair value on the date of the grant and recognizes compensation expense of those awards over the requisite service period, which is generally the vesting period of the respective award. The Company records the expense for these awards using the straight-line method over the service period. The Company recognizes adjustments to stock-based compensation expense for forfeitures as they occur. The Company classifies stock-based compensation expenses in its statements of operations in the same manner in which the award recipient's payroll costs are classified or in which the award recipients' service payments are classified.

The fair value of each stock option and other stock-based awards are estimated on the date of grant using the Black-Scholes option-pricing model. Inputs used in the Black-Scholes option-pricing model are summarized as follows:

Expected Term: The expected term is calculated using the simplified method. The simplified method calculates the expected term as the average of the vesting and contractual terms of the award. The Company elected to use the simplified method because of its limited history of stock option exercise activity.

Expected Volatility: As the Company does not have sufficient trading history to estimate the volatility of its common stock, the expected volatility was estimated by taking the average historic price volatility for industry peers, consisting of several public companies in the Company's industry which are either similar in size, stage of life cycle, or financial leverage, over a period equivalent to the expected term of the awards, where available.

Risk-Free Interest Rate: The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award.

Expected Dividend Yield: The Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future. Accordingly, estimated dividend yield is zero.

The fair value for each restricted common stock award and nominal exercise price warrants were estimated on the date of grant based on the most recent calculation of fair value of the Company's common stock. Subsequent to the Company's IPO, the fair value is based on the closing price of the Company's common stock on the grant date.

Common Stock Warrants and Warrant Liability

The Company accounts for common stock warrants issued as freestanding instruments in accordance with applicable accounting guidance as either liabilities or as equity instruments depending on the specific terms of the warrant agreement. Warrants that are classified as liabilities are initially recorded at fair value and remeasured at fair value at each balance sheet date until settlement. Changes in the fair value of warrant liabilities are recorded in change in fair value of derivative instruments in the statements of operations. The Company determines the fair value of warrant liabilities using valuation techniques that maximize the use of observable inputs. For warrant liabilities with nominal or low exercise prices, fair value is generally determined using observable inputs, primarily the quoted closing price of the

Company's common stock at the measurement date, together with fixed contractual terms (including the exercise price). For other warrant liabilities, fair value is estimated using an option pricing model (for example, the Black-Scholes model), which may require inputs such as expected volatility, expected term, risk-free interest rate, and expected dividend yield. Expected volatility may be estimated using the historical volatilities of comparable public companies when the Company does not have sufficient trading history. Warrant liabilities valued using observable inputs are generally classified within Level 2 of the fair value hierarchy. Warrant liabilities that use significant unobservable inputs are classified within Level 3 of the fair value hierarchy. Different warrant tranches may be classified within different levels of the fair value hierarchy depending on the observability of the significant inputs used in the valuation. See Note 3 *Fair Value Measurements* for a description of these assumptions.

Redeemable Convertible Preferred Stock

The Company recorded all shares of redeemable convertible preferred stock at their respective fair values on the dates of issuance, net of issuance costs. The redeemable convertible preferred stock were recorded outside of permanent equity because upon the occurrence of certain deemed liquidation events, the majority of the holders could opt to redeem the shares at the liquidation preference and these events, including a merger, acquisition or sale of substantially all of the assets, are considered not solely within the Company's control. The Company did not adjust the carrying values of the redeemable convertible preferred stock to its redemption value because it was not considered redeemable as of December 31, 2024. During the year ended December 31, 2025, the Company did not accrete the carrying values of the redeemable convertible preferred stock to the liquidation preference, as the IPO triggered automatic conversion to common stock rather than a redemption event. No deemed liquidation events were probable during the period. Immediately prior to the IPO closing, the outstanding shares of redeemable convertible preferred stock were adjusted for the 1-for-27.8874 reverse stock split, and the Series C preferred stock was further adjusted for anti-dilution provisions. Upon closing of the IPO in September 2025, all 78,072,306 shares of redeemable convertible preferred stock (as adjusted) automatically converted into 3,191,334 shares of common stock, including 391,986 shares issued pursuant to anti-dilution adjustments. The conversion was recorded at the aggregate carrying value of $114.3 million, which was reclassified from temporary equity to additional paid-in capital.

Research and Development

Research and development costs include expenditures in connection with clinical trials, employee cash and stock-based compensation, regulatory and scientific consulting fees, contract research for preclinical studies, drug formulation, manufacturing, supply and handling and data collection. Advance payments for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. The prepaid amounts are expensed as the related goods are delivered or the services are performed.

The value of goods and services received from contract research organizations ("CROs") and other third parties are accrued each reporting period based on estimates of the level of services performed and progress in the period when invoices have not been received from such organizations. When evaluating the adequacy of the accrued liabilities, the progress of the studies or clinical trials are analyzed, including the phase or completion of events, invoices received and contracted costs. Significant judgments and estimates are made in determining the accrued balances at the end of any reporting period. Accruals are adjusted as actual costs become known or as additional information becomes available.

General and Administrative

General and administrative costs include expenditures that are not directly related to research and development. General and administrative costs include costs for support and administrative functions including salaries and benefits, stock-based compensation and other personnel-related costs. Additional costs include non-personnel costs such as legal and professional fees, rent, audit fees, insurance costs and public company-related expenses.

Patents and Trademarks

The Company expenses external costs, such as filing fees and associated attorney fees, incurred to obtain issued patents and trademarks and patent and trademark applications pending. The Company also expenses costs associated with maintaining and defending patents and trademarks subsequent to their issuance in the period incurred.

Income Taxes

Income taxes have been determined using the asset and liability approach of accounting for income taxes. Under this approach, deferred taxes represent the future tax consequences expected to occur when the reported amounts of assets and liabilities are recovered or paid. Deferred taxes result from differences between the financial statement and tax bases of LB's assets and liabilities and are adjusted for changes in tax rates and tax laws when changes are enacted. Valuation allowances are recorded to reduce deferred tax assets when it is more likely than not that a tax benefit will not be realized. The assessment of whether a valuation allowance is required often requires significant judgment.

Net Loss Per Share

The Company follows the two-class method when computing net loss per share, as the Company has issued shares that meet the definition of participating securities. The two-class method determines net loss per share for each class of common and participating securities according to dividends declared or accumulated and participation rights in undistributed earnings. The two-class method requires income available to common stockholders for the period to be allocated between common and participating securities based upon their respective rights to receive dividends as if all income for the period had been distributed.

Basic net loss per share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted average number of shares of common stock outstanding for the period. Diluted net loss attributable to common stockholders is computed by adjusting loss attributable to common stockholders to reallocate undistributed earnings based on the potential impact of dilutive securities, including outstanding stock options. Diluted net loss per share attributable to common stockholders is computed by dividing the diluted net loss attributable to common stockholders by the weighted average number of common shares outstanding for the period, including potential dilutive common shares assuming the dilutive effect of outstanding stock options.

Comprehensive Loss

Comprehensive loss includes net loss, as well as other changes in stockholders' deficit that result from transactions and economic events other than those with stockholders. For the years ended December 31, 2025 and 2024, the Company's only element of other comprehensive loss was unrealized gain/loss on marketable securities.

Recently Issued Accounting Pronouncements Not Yet Adopted

In December 2023, the Financial Accounting Standards Board ("FASB") issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures* which requires enhanced income tax disclosures, including a tabular rate reconciliation using specified categories with disaggregated information for significant reconciling items that meet a quantitative threshold, and disclosure of income taxes paid disaggregated by federal, state and foreign jurisdictions. For public business entities, the guidance is effective for annual periods beginning after December 15, 2024. As the Company has elected the extended transition period available to emerging growth companies under the JOBS Act, the guidance is effective for the Company for fiscal years beginning after December 15, 2025, and the Company expects to adopt ASU 2023-09 for its fiscal year ending December 31, 2026. Early adoption is permitted. As the standard impacts disclosure requirements only and does not affect recognition or measurement, the Company does not expect adoption to have a material impact on its financial position or results of operations but does expect expanded income tax disclosures upon adoption.

In November 2024, the FASB issued ASU 2024-03 *Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses*, which requires public business entities to provide disaggregated disclosures of certain income statement expense line items on an annual and interim basis, including the amounts of employee compensation, depreciation, amortization and depletion, and other specified cost categories included in each relevant expense caption. The guidance applies only to public business entities and is effective for annual reporting periods beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027. Early adoption is permitted. The Company is evaluating the impact the adoption of this guidance will have on its financial statement disclosures.

In December 2025, the FASB issued ASU 2025-11, *Interim Reporting (Topic 270): Narrow-Scope Improvements* which reorganizes and clarifies the interim disclosure requirements in ASC 270 to improve usability and clarify when interim reporting guidance applies. The ASU also introduces a disclosure principle requiring entities to describe events occurring after the end of the most recent annual reporting period that have a material impact on the interim period. The standard does not change the fundamental nature or quantity of interim disclosures required under GAAP. For public business entities, the guidance is effective for interim periods within fiscal years beginning after December 15, 2027. For all other entities, the guidance is effective for interim periods within fiscal years beginning after December 15, 2028. As the Company has elected the extended transition period available to emerging growth companies under the JOBS Act, the Company expects to adopt this guidance for interim periods within fiscal years beginning after December 15, 2028. Early adoption is permitted. The Company does not expect adoption to have a material impact on its financial statements or disclosures.

3. Fair Value Measurements

The following table presents the Company's assets and liabilities that are measured at fair value on a recurring basis classified under the appropriate level of the fair value hierarchy (in thousands):

	As of December 31, 2025			
	Fair Value Measurement Using			
	Level 1	Level 2	Level 3	Total
Assets				
Cash equivalents				
Money market funds	$ 249,393	$ —	$ —	$ 249,393
Total cash equivalents	**249,393**	**—**	**—**	**249,393**
Marketable securities				
Government securities	—	45,040	—	45,040
Total marketable securities	**—**	**45,040**	**—**	**45,040**
Restricted cash				
Certificate of deposit	—	770	—	770
Total restricted cash	**—**	**770**	**—**	**770**
Total assets	**$ 249,393**	**$ 45,810**	**$ —**	**$ 295,203**
Liabilities				
Derivative liability - warrants	—	1,305	38	1,343
Total liabilities	**$ —**	**$ 1,305**	**$ 38**	**$ 1,343**

	As of December 31, 2024			
	Fair Value Measurement Using			
	Level 1	Level 2	Level 3	Total
Assets				
Cash equivalents				
Money market funds	$ 19,926	$ —	$ —	$ 19,926
Total cash equivalents	**19,926**	—	—	**19,926**
Marketable securities				
Government securities	—	5,021	—	5,021
Total marketable securities	**—**	**5,021**	**—**	**5,021**
Restricted cash				
Certificate of deposit	—	498	—	498
Total restricted cash	**—**	**498**	**—**	**498**
Total assets	**$ 19,926**	**$ 5,519**	**$ —**	**$ 25,445**
Liabilities				
Derivative liability - warrants	—	—	2,504	2,504
Total liabilities	**$ —**	**$ —**	**$ 2,504**	**$ 2,504**

Marketable Securities

The Company accounts for marketable securities held as "available-for-sale" in accordance with ASC 320, *Investments-Debt Securities*. The Company classifies these investments as current assets and carries them at fair value.

The fair value of the Company's marketable securities classified within Level 2 is based upon observable inputs that may include benchmark yields, reported trades, broker/dealer quotes, issuer spreads, two-sided markets, benchmark securities, bids, offers, and reference data including market research publications.

Certificate of Deposit

The Company's certificates of deposit are Level 2 instruments. The fair value of such instruments is estimated based on valuations obtained from third-party pricing services that utilize industry standard valuation models, including both income-based and market-based approaches, for which all significant inputs are observable either directly or indirectly. These inputs include interest rate curves, foreign exchange rates, and credit ratings.

Warrants

The Company has issued warrants to investors in connection with prior equity financings. These warrants are required to be measured at fair value and presented as liabilities in the accompanying balance sheets. As of December 31, 2025, the warrant liabilities include (i) nominal exercise price warrants, which are marked-to-market based on the period-end closing price of the Company's common stock and (ii) the New Series B Warrant, which has an exercise price of $41.83 and is valued using the Black‑Scholes option pricing model, which includes unobservable inputs. The nominal exercise price warrants are classified within Level 2 of the fair value hierarchy. The New Series B Warrant is classified within Level 3. See Note 8 *Redeemable Convertible Preferred Stock and Equity* for additional information on the warrants.

For the years ended December 31, 2025 and 2024, the change in the fair value of the Level 3 warrant liability resulted in the recording of a gain (loss) on change in fair value of derivative instruments of $0.04 million and ($0.9) million, respectively, in the accompanying statements of operations.

The following are the assumptions used in the Black-Scholes valuation model in order to determine the fair value of the Level 3 derivative liabilities for the warrant liabilities for the years ended December 31, 2025 and 2024:

		December 31, 2025	December 31, 2024
Term		2.66	0.58 - 2.00
Volatility		103.4%	49.0% - 70.0 %
Exercise price	$	41.83	$ 0.28 - $41.83
Risk-free rate		3.52%	4.23% - 4.25 %

If the significant unobservable inputs of volatility and discount rate were to change, this may result in a significantly higher or lower fair value measurement at the reporting dates. The changes in Level 3 derivative liabilities for the years ended December 31, 2025 and 2024 were as follows (in thousands):

		Warrants
Balance, December 31, 2023	**$**	**1,557**
Loss due to change in fair value		947
Balance, December 31, 2024	**$**	**2,504**
Transfer of nominal exercise price warrants out of Level 3 into Level 2		(2,426)
Gain due to change in fair value		(40)
Balance, December 31, 2025	**$**	**38**

The change in the total warrant liabilities for the years ended December 31, 2025 and 2024 was (in thousands):

		Warrants
Balance, December 31, 2023	**$**	**1,557**
Loss due to change in fair value		947
Balance, December 31, 2024	**$**	**2,504**
Gain due to change in fair value		(1,161)
Balance, December 31, 2025	**$**	**1,343**

During the year ended December 31, 2025, the Company transferred certain warrant liabilities from Level 3 to Level 2 within the fair value hierarchy. Transfers between levels are recognized at the beginning of the reporting period in which the transfer occurs.

There are uncertainties on the fair value measurement of the instruments classified under Level 3 due to the use of unobservable inputs and interrelationships between these unobservable inputs, which could result in higher or lower fair value measurements.

4. Cash Equivalents, Marketable Securities and Restricted Cash

The Company invests in certain U.S. government money market funds and treasury bills classified as cash equivalents and invests in certificate of deposits that are classified as restricted cash. The marketable securities consist of government securities as follows (in thousands):

	As of December 31, 2025			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Aggregate Fair Value
Cash equivalents				
Money market funds	$ 249,393	$ —	$ —	$ 249,393
Total cash equivalents	**249,393**	**—**	**—**	**249,393**
Marketable securities				
Government securities	44,872	168	—	45,040
Total marketable securities	**44,872**	**168**	**—**	**45,040**
Restricted cash				
Certificate of deposit	770	—	—	770
Total cash equivalents, marketable securities and restricted cash	**$ 295,035**	**$ 168**	**$ —**	**$ 295,203**

	As of December 31, 2024			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Aggregate Fair Value
Cash equivalents				
Money market funds	$ 19,926	$ —	$ —	$ 19,926
Total cash equivalents	**19,926**	**—**	**—**	**19,926**
Marketable securities				
Government securities	4,910	111	—	5,021
Total marketable securities	**4,910**	**111**	**—**	**5,021**
Restricted cash				
Certificate of deposit	498	—	—	498
Total cash equivalents, marketable securities and restricted cash	**$ 25,334**	**$ 111**	**$ —**	**$ 25,445**

The contractual maturities of the Company's marketable securities are summarized as follows (in thousands):

	As of December 31, 2025			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Aggregate Fair Value
Within one year	$ 23,254	$ 109	$ —	$ 23,363
After one year to five years	21,618	59	—	21,677
Total marketable securities	**$ 44,872**	**$ 168**	**$ —**	**$ 45,040**

As of December 31, 2025 and 2024, there were no available-for-sale securities that have been in a continuous unrealized loss position for more than 12 months. For the years ended December 31, 2025 and 2024, the net unrealized holding gain (loss) on available-for-sale securities included in accumulated other comprehensive income was $0.1 million and $(0.2) million, respectively, and gains of $0.1 million and $1.0 million, respectively, were reclassified out of accumulated other comprehensive income into earnings upon the sale of available-for-sale securities.

A reconciliation of the cash, cash equivalents and restricted cash reported in the balance sheets that sum to the total of the amounts shown in the statements of cash flows is as follows (in thousands):

	As of December 31,	
	2025	2024
Cash and cash equivalents	$ 250,173	$ 22,978
Restricted cash	770	498
Total cash, cash equivalents and restricted cash	**$ 250,943**	**$ 23,476**

5. Property and Equipment, Net

Property and equipment, net consisted of the following as of December 31, 2025 and 2024 (in thousands):

	December 31, 2025	December 31, 2024
Leasehold improvements	$ 1,491	$ 1,491
Computer equipment	130	95
Office furniture	380	374
Property and equipment	**2,001**	**1,960**
Less: accumulated depreciation	(420)	(101)
Total property and equipment, net	**$ 1,581**	**$ 1,859**

Depreciation and amortization expense totaled $0.3 million and $0.1 million for the years ended December 31, 2025 and 2024, respectively, and is recorded in general and administrative expense in the accompanying statements of operations.

6. Prepaid Expenses and Other Current Assets and Accrued Expenses

Prepaid expenses consisted of the following as of December 31, 2025 and 2024 (in thousands):

	December 31, 2025	December 31, 2024
CRO advances	$ 10,757	$ 422
Prepaid research and development	541	269
Prepaid clinical trial expenses	750	—
Prepaid insurance	693	57
Other prepaid expenses and other current assets	478	132
Total prepaid expenses and other current assets	**$ 13,219**	**$ 880**

Accrued expenses consisted of the following as of December 31, 2025 and 2024 (in thousands):

	December 31, 2025	December 31, 2024
Accrued CRO costs	$ 1,324	$ 1,443
Accrued research and development costs	449	488
Accrued compensation costs	1,680	1,441
Accrued professional and consulting costs	350	902
Accrued termination benefits	515	800
Other accrued costs	267	228
Total accrued expenses	**$ 4,585**	**$ 5,302**

During the year ended December 31, 2024, the Company wrote off $3.2 million of deferred offering costs that were previously included in prepaid expenses and other current assets. The write-off was recorded in general and administrative expenses in the accompanying statements of operations for the year ended December 31, 2024.

7. Leases

In May 2024, the Company entered into a new lease agreement for office space in New York, New York. The Company received $1.2 million of leasehold improvement incentives associated with the new lease agreement. The term of this lease commenced on June 21, 2024, which is the date the Company obtained control over the leased premises. The lease term continues through March 2032. The Company's real estate lease agreement includes variable payments that are passed through by the landlord, such as insurance, taxes, and common area maintenance, and payments based on the usage of the asset. Pass-through charges and payments due to changes in usage of the asset are included within variable rent expense. Operating leases are recognized over the lease term and included in general and administrative expenses in the accompanying statements of operations. Variable lease expenses are recognized in general and administrative expenses in the accompanying statements of operations as incurred.

The Company's lease agreement does not contain material residual value guarantees, restrictions, or covenants. The Company has no other operating leases recognized on the accompanying balance sheets.

On November 10, 2025, the Company entered into an amendment to the lease agreement providing for the lease of approximately 4,600 square feet of additional office space through March 2032. The amendment did not result in any changes in terms of the original leased space. The Company determined the lease for additional space is treated as a separate lease and recorded when access to the new space is granted per ASC 842. The additional office space is expected to be delivered to the Company on or before July 1, 2026. The fixed rent for the additional office space will be $2.6 million over the remaining term.

The components of lease expense were as follows for the years ended December 31, 2025 and 2024 (in thousands):

	December 31, 2025	December 31, 2024
Operating lease expense	$ 534	$ 308
Short-term lease expense	—	119
Variable lease expense	27	—
Total lease expense	**$ 561**	**$ 427**

Short-term lease expense includes expenses related to the Company's 2018 operating lease agreement for office space in New York, New York. The lease agreement was month-to-month and could be terminated by either party with three months' written notice. The Company terminated the lease effective September 30, 2024. The Company made the policy election to exclude short-term leases from recognition and measurement under ASC 842.

Supplemental balance sheet information related to operating leases as of December 31, 2025 and 2024 was as follows (in thousands):

	December 31, 2025	December 31, 2024
Operating lease right-of-use assets	$ 2,151	$ 2,298
Operating lease liability, current	730	487
Operating lease liability, noncurrent	2,839	3,216
Total operating lease liability	$ 3,569	$ 3,703
Weighted average remaining lease term (in years)	6.3	7.3
Weighted average discount rate	9.6 %	9.6 %

Other information related to leases for the years ended December 31, 2025 and 2024 was as follows (in thousands):

	December 31, 2025	December 31, 2024
Cash paid for amounts included in the measurement of lease liabilities	$ 520	$ 61

As of December 31, 2025, future minimum commitments under operating leases were as follows (in thousands)[1]:

Year Ending December 31,	As of December 31, 2025
2026	$ 730
2027	730
2028	764
2029	775
2030	775
Thereafter	968
Total future lease payments	$ 4,742
Less: imputed interest	(1,173)
Present value of lease payments	$ 3,569

(1) The table excludes approximately $2.6 million of minimum lease payments for the additional leased space for which a contract has been signed, but has not yet commenced.

8. Redeemable Convertible Preferred Stock and Equity

The Company's Amended and Restated Certificate of Incorporation designates and authorizes the Company to issue up to 510.0 million shares, consisting of: (i) 500.0 million shares of common stock, par value $0.0001 per share; and (ii) 10.0 million shares of preferred stock, par value $0.0001 per share.

Redeemable Convertible Preferred Stock

The Company's redeemable convertible preferred stock ("Preferred Stock") was converted to common stock as part of the IPO (see Note 1 *Business Overview* for additional information). As of December 31, 2024, the Company's redeemable convertible preferred stock consisted of the following (in thousands, except per share data):

	As of December 31, 2024					
	Issuance Start Date	Shares Authorized (1)	Shares Issued and Outstanding (2)	Issuance Price Per Share (1)	Net Carrying Value	Liquidation Preference
Series Seed	11/21/2017	295	295	$ 1.50	$ 435	$ 443
Series A	11/21/2018	3,655	3,655	$ 2.30	6,179	8,407
Series B	5/3/2022	301	301	$ 3.00	580	903
Series C	8/29/2023	75,000	73,820	$ 1.50	107,065	110,731
		79,251	78,071		$ 114,259	$ 120,484

(1) Shares authorized, shares issued and outstanding and price per share are not adjusted for the reverse stock split detailed in Note 1 *Business Overview*.

As of December 31, 2024, none of the outstanding shares of Preferred Stock had been converted into common stock.

Reissuance: Shares of any Preferred Stock that are redeemed or converted will be retired or canceled and may not be reissued by the Company.

Common Stock

All issued shares of common stock are entitled to vote on a one share/one vote basis.

During 2024, the Company entered into an agreement for financial advisory services. As compensation for the services, the Company issued 1,433 shares of common stock. The Company recorded stock-based compensation expense of $0.1

million included in general and administrative expense on the accompanying statement of operations. The fair value of the issued shares was determined based on the fair value of the Company's common stock as of the date of the agreement.

Warrants

In 2018, in connection with the Company's Series A Offering in 2018 (the "Series A Offering"), the Company issued warrants to purchase 0.06 million shares of the Company's common stock at an exercise price of $64.14 per share. The warrants expire ten years after issuance. The warrants were issued in two tranches of which 0.03 million were fully exercisable at issuance ("Class A Warrants") and the remaining 0.03 million were exercisable as of May 21, 2022 ("Class B Warrants").

In May 2022, in connection with the Company's Series B preferred stock financing (the "Series B Offering"), the Company issued warrants to purchase 2,868 shares of the Company's common stock that were immediately exercisable ("Series B-1 Warrants"). The Series B-1 Warrants expire five years after issuance. The Series B Offering includes a Rights Offer in which participants in the Series A Offering were offered the opportunity to invest in the Series B Offering. Class A Warrant holders who participated received the right to convert their Class A Warrants into common stock at no cost. On May 3, 2022, less than 0.01 million Class A Warrants were converted into common stock. Pursuant to anti-dilution provisions, the exercise price of the remaining Class A Warrants was reduced from $64.14 to $63.30 per share as a result of the conversions.

In August 2023, as part of the Company's Series C preferred stock financing (the "Series C Offering"), the Company modified the outstanding Class A Warrants, Class B Warrants, and Series B-1 Warrants, reducing the exercise price to $0.28 per share. Additionally, the Company issued less than 0.01 million warrants to Series B preferred stockholders at an exercise price of $41.83 per share, allowing the holders to purchase common stock in an amount equal to 33.33% of their Series B preferred holdings (the "New Series B Warrants"). The New Series B Warrants were immediately exercisable and expire five years after issuance. The issuance of the New Series B Warrants was accounted for as an inducement under ASC 470-20, and the Company recorded financing costs based on the grant date fair value of the New Series B Warrants.

From 2020 through 2023, the Company granted warrants to a placement agent for services provided in connection with the issuance of convertible notes and various equity financings (the "Placement Agent Warrants"). In August 2023, in connection with the Series C Offering, the exercise price of the outstanding Placement Agent Warrants was reduced to $0.28 per share. The placement agent warrants expire in August 2033.

As of December 31, 2025, the Class A Warrants, Class B Warrants, Series B-1 Warrants and Placement Agent Warrants each have an exercise price of $0.28 per share. As the exercise price is nominal relative to the fair value of the underlying common stock, these nominal exercise price warrants are included in basic weighted average shares outstanding (see Note 9, *Net Loss Per Share*). The Class A Warrants, Class B Warrants, Series B-1 Warrants, and New Series B Warrants are classified as liabilities. The placement agent warrants are classified as equity. See Note 3, *Fair Value Measurements*, for information regarding valuation methodology, fair value hierarchy classification, Level 3 rollforward activity, and assumptions used in the valuation of the warrant liabilities.

During the year ended December 31, 2025, warrants were exercised resulting in the issuance of 464 shares of the Company's common stock. During the year ended December 31, 2024, warrants were exercised, resulting in the issuance of 253 shares of the Company's common stock. There were no modifications to any issuance of the warrants during the years ended December 31, 2025 or 2024.

Warrants outstanding as of December 31, 2025 and 2024 are as follows:

	As of December 31,	
	2025	2024
Class A Warrants	24,687	24,919
Class B Warrants	31,373	31,605
Series B-1 Warrants	2,557	2,557
New Series B Warrants	3,509	3,509
Placement agent warrants	54,813	54,813
Total warrants outstanding	**116,939**	**117,403**

See Note 3 *Fair Value Measurements* for warrant activity for the years ended December 31, 2025 and 2024.

9. Net Loss per Share

The following table sets forth the computation of basic and diluted net loss per share of common stock for the years ended December 31, 2025 and 2024 (in thousands, except share and per share data):

	Year ended December 31,	
	2025	2024
Net loss	$ (25,205)	$ (63,102)
Weighted average common shares used in computing net loss per share, basic and diluted [(1)]	8,045,145	358,229
Net loss per share, basic and diluted	**$ (3.13)**	**$ (176.15)**

(1) Included within weighted average common shares outstanding for the years ended December 31, 2025 and 2024 are 113,430 and 114,004, respectively, common shares issuable upon the exercise of warrants with nominal exercise pricing. Per ASC 260, *Earnings Per Share*, the warrants are exercisable at any time for nominal consideration, and as such, the shares are considered outstanding for the purpose of calculating basic and diluted net loss per share attributable to common stockholders.

The Company's potentially dilutive securities, which consist primarily of stock options and convertible preferred stock, have been excluded from the computation of diluted net loss per share because including them would have had an anti-dilutive impact. Therefore, the weighted average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same.

The following common stock equivalents, presented based on amounts outstanding at each period end, have been excluded from the calculation of diluted net loss per share because including them would have an antidilutive effect (in thousands):

	December 31, 2025	December 31, 2024
Redeemable convertible preferred stock	—	2,799
Restricted stock - unvested	7	6
Common stock warrants	3	3
Stock options	2,588	457
Total common stock equivalents	2,598	3,265

10. Stock-Based Compensation

The Company uses equity-based compensation programs to provide long-term performance incentives for its employees, directors and consultants. These incentives consist primarily of stock options and restricted stock grants.

In January 2017, the Company's Board of Directors approved the LB Pharmaceuticals Inc 2017 Stock Incentive Plan ("2017 Plan"). No additional shares will be issued under the 2017 Plan. As of December 31, 2025 and 2024, there were 2,150 and 10,397 shares outstanding, respectively.

In 2018, the Company's Board of Directors approved the LB Pharmaceuticals Inc 2018 Stock Incentive Plan ("2018 Plan"). No additional awards will be granted under the 2018 Plan. As of December 31, 2025 and 2024, there were 20,234 and 27,943 shares outstanding, respectively.

In August 2023, the Company's Board of Directors approved the LB Pharmaceuticals Inc 2023 Stock Incentive Plan ("2023 Plan"). The 2023 Plan authorized the issuance of stock options or restricted stock up to 288,847 shares of the Company's common stock. In December 2024, the Company amended the 2023 Plan increasing the maximum aggregate number of shares that may be issued under the 2023 Plan to 464,553. No additional shares will be issued under the 2023 Plan. As of December 31, 2025 and 2024, there were 397,385 and 457,138 shares outstanding under the 2023 Plan, respectively.

In September 2025, the Company's stockholders approved the LB Pharmaceuticals Inc 2025 Equity Incentive Plan ("2025 Plan"). The 2025 Plan authorized the issuance of stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards and performance awards. Initially, the maximum number of shares issuable under the 2025 Plan is 2,907,335 shares. In addition, the number of shares reserved for issuance under the 2025 will increase on January 1 of each calendar year, starting on January 1, 2026 through January 1, 2035, in an amount equal to 5% of the total number of fully diluted shares on the last day of the year prior to the date of the automatic increase, or a lesser amount as determined by the board of directors. The maximum number of shares of common stock that may be issued on the exercise incentive stock options under the 2025 Plan is 8,722,005. As of December 31, 2025, there were 1,882,871 shares outstanding under the 2025 Plan. As of December 31, 2025, 605,412 shares are available for future issuance under the 2025 Plan.

Issuances Outside of Equity Plans

During the year ended December 31, 2025, the Company granted employees 285,000 stock options as an inducement material to the acceptance of an offer of employment in accordance with Nasdaq Listing Rule 5635(c)(4). The Company intends to file a registration statement on Form S-8 to register the shares of common stock underlying the inducement awards.

Stock Options

Stock options vest based on one of the following schedules: (i) 25% on the first anniversary of grant date with the remaining 75% to vest in 36 equal monthly installments thereafter through the fourth anniversary of the grant date; (ii) 100% vesting in 36 equal monthly installments through the third anniversary of the grant date; or (iii) 100% vesting in 12 equal monthly installments through the first anniversary of the grant date for certain nonemployee grants. All stock options expire ten years from the grant date. The assumptions used to determine the fair value of stock options granted to employees and non-employees for the years ended December 31, 2025 and 2024 were as follows:

	December 31, 2025	December 31, 2024
Expected life of options (in years)	5.83 - 6.25	6.25 - 10.00
Risk-free interest rate	3.67% - 4.42%	4.20% - 4.56 %
Expected volatility	76.5% - 96.3%	82.1% - 86.4 %
Dividends	—%	—%
Fair value of common stock	$14.61-$35.14	$ 31.23 - $49.65

A summary of the Company's stock option activity and related information is as follows:

	Options Outstanding (in thousands)	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Balance at December 31, 2024	457	$ 43.50	9.01	—
Granted	2,205	$ 15.66		—
Forfeited	(68)	$ 45.20		—
Exercised	(6)	$ 41.84		—
Balance at December 31, 2025	2,588	$ 15.77	9.46	$ 17,235
Options vested and expected to vest as of December 31, 2025	2,588	$ 15.77	9.46	
Options exercisable as of December 31, 2025	159	$ 18.25	7.70	

The weighted average grant date fair value of the stock options granted during the year ended December 31, 2025 was $11.42. The weighted average grant date fair value of the stock options granted during the year ended December 31, 2024 was $31.23.

During the years ended December 31, 2025 and 2024. the Company recognized stock-based compensation expense related to stock options as follows (in thousands):

	Year ended December 31,	
	2025	2024
Research and development	$ 759	$ 396
General and administrative	3,352	2,691
Total stock-based compensation expense	**$ 4,111**	**$ 3,087**

As of December 31, 2025, there was $29.1 million unrecognized stock-based compensation expense which is expected to be recognized over a weighted average period of 3.56 years.

As of December 31, 2024, the Company's former chief executive officer (the "Former CEO") entered into a transition, consulting, and separation agreement ("Separation Agreement") with the Company including continued consulting services (see Note 11 *Restructuring*). Pursuant to the original terms of the stock option awards, the outstanding stock options continue to vest as long as services are provided to the Company under the Separation Agreement as a non-employee consultant. In accordance with ASC 718, there was a modification of the Former CEO's options related to a reduction in the level of required service. The consulting services outlined in the Separation Agreement are not substantive. As a result, the Company determined the fair market value of all awards expected to vest over the duration of the Separation Agreement as of the modification date using the Black-Scholes option pricing model. The total amount of $1.7 million was recognized immediately.

In connection with a reduction in force ("RIF") initiated in May 2025, the Company modified stock option awards granted to its former Chief Financial Officer ("Former CFO") and former Chief Scientific Officer ("Former CSO"). These modifications involve the acceleration of service-based vesting conditions and were accounted for as Type III modifications (improbable-to-probable vesting) in accordance with ASC 718. During the year ended December 31, 2025, the Company recognized a reduction of $0.2 million in stock-based compensation expense included in general and administrative expense and an increase of less than $0.1 million included in research and development expense on the statement of operations.

The fair value of the modified stock options was remeasured as of May 6, 2025 using the Black-Scholes option pricing model, incorporating the following assumptions:

	May 6, 2025
Expected life of options (in years)	0.25 - 0.56
Risk-free interest rate	4.42%
Expected volatility	86.70%
Dividends	—%
Fair value of common stock	$ 22.03

In connection with the IPO in September 2025, the Company's board of directors approved the repricing of stock options previously granted to current executive officers, employees and directors with per-share exercise prices above the initial per share to the public price in the offering, or the Option Repricing. Based on the initial price per share to the public of $15.00 per share, on September 10, 2025, stock options to purchase 406,998 shares of common stock were automatically repriced to an exercise price per share of $15.00. These modifications were accounted for as a Type I modification (probable-to-probable vesting) in accordance with ASC 718. During the year ended December 31, 2025, the Company recognized stock based compensation expense of $0.1 million in research and development expenses and $0.4 million in general and administrative expenses in the statements of operations. The Company will recognize an additional $1.1 million through February 2029.

The fair value of the modified stock options was remeasured as of September 10, 2025 using the Black-Scholes option pricing model, incorporating the following assumptions:

	September 10, 2025
Expected life of options (in years)	1.40 - 5.79
Risk-free interest rate	3.51% - 3.66 %
Expected volatility	50.0%
Dividends	—%
Fair value of common stock	$ 15.00

There were no realized tax benefits for the years ended December 31, 2025 and 2024.

Restricted Stock

No restricted stock was granted during the years ended December 31, 2025 and 2024.

Restricted stock awards vest over the period in which the related services are rendered, which may range from immediate vesting to up to 36 months. Certain awards alternatively vest upon the consummation of the Company’s first underwritten public offering under the Securities Act of 1933, or on the six month anniversary of the public offering.

A summary of the Company’s restricted stock activity is as follows:

	Shares (in thousands)	Weighted Average Grant Date Fair Value
Unvested Balance at December 31, 2024	7	$ 11.15
Granted	—	$ —
Vested	—	$ —
Unvested balance as of December 31, 2025	7	$ 11.15

During the years ended December 31, 2025 and 2024, the Company recognized stock-based compensation related to shares of restricted stock as follows (in thousands):

	Year ended December 31,	
	2025	2024
Research and development	$ 2	$ 2
General and administrative	78	1
Total stock-based compensation expense	**$ 80**	**$ 3**

As of the closing of the IPO in September 2025, the Company recognized approximately $0.1 million for awards that vest upon the consummation of the Company's first underwritten public offering under the Securities Act of 1933 or the six month anniversary of the IPO. Substantially all of the compensation expense related to these awards has been recognized as of December 31, 2025.

11. Restructuring

On May 6, 2025, the Company commenced a RIF. This initiative affected several employees, including the Former CFO and the Former CSO. The RIF was designed to streamline operations while ensuring continuity during the transition period.

In connection with the RIF, the Company entered into separation agreements with impacted employees that provided the impacted employees to termination benefits, with benefit terms expiring at various dates through May 30, 2026. These benefits included the continuation of base salary, then in effect, and the payment of monthly premiums for Company-sponsored healthcare coverage. The Former CFO and Former CSO also received accelerated vesting on outstanding stock option awards. See Note 10 *Stock-Based Compensation* for additional information on the stock option modifications.

The Company expects to incur total restructuring charges of approximately $0.7 million, primarily related to termination benefits, partially offset by a reduction in stock-based compensation expenses.

During the year ended December 31, 2025, the Company recognized $0.4 million in general and administrative expense and $0.5 million in research and development expense, in the statement of operations related to termination benefits under the various separation agreements. The modification of the Former CFO's and Former CSO's stock options resulted in a reduction of $0.2 million in stock-based compensation expense included in general and administrative expense and an increase of less than $0.1 million included in research and development expense in the statement of operations during the year ended December 31, 2025.

All restructuring costs associated with the RIF were recognized in the second quarter of 2025, when the plan was communicated to affected employees and obligations were incurred. The remaining severance payments, which were accrued as of December 31, 2025, are expected to be paid through May 2026.

On November 26, 2024, the Company's former chief executive officer (the "Former CEO") entered into a separation and consulting agreement ("Separation Agreement"), pursuant to which the Former CEO resigned from his role as CEO. Under the Separation Agreement, the Former CEO is entitled to termination benefits until June 30, 2026, in the form of continuation of base salary in the same amount in effect as of December 31, 2024 and the payment of monthly premiums for healthcare coverage. As of December 31, 2024, the Company recorded $0.8 million of accrued termination benefits in the balance sheet.

The following table provides a reconciliation of the beginning and ending liability balances for the year ended December 31, 2025 (in thousands):

Balance, December 31, 2024	$ 800
Termination benefit expense	896
Cash payments	(1,181)
Balance, December 31, 2025	**$ 515**

12. Income Taxes

The provision from income taxes for the years ended December 31, 2025 and 2024 is as follows (in thousands):

	Year ended December 31,	
Current:	**2025**	**2024**
Federal	$ —	$ —
State	1	1
Total current tax expense	**1**	**1**
Deferred:		
Federal	—	—
State	—	—
Total deferred tax expense	—	—
Income tax provision	**$ 1**	**$ 1**

A reconciliation of the effective tax rates of the Company and the U.S. federal statutory tax rate is as follows:

	Year ended December 31,	
	2025	**2024**
Statutory tax rate	**21.0%**	**21.0%**
Changes in income taxes resulting from:		
State taxes (net of federal tax benefits)	0.3%	(5.1%)
Increase in valuation allowance	(24.9)%	(17.9)%
Non-deductible interest and other expenses	(2.1)%	(1.1)%
Return to provision adjustments	3.9 %	(0.2)%
Tax credits	1.8 %	3.3 %
Effective income tax rate	**— %**	**— %**

The temporary differences of the Company that give rise to significant portions of the Company's deferred tax assets and liabilities as of December 31, 2025 and 2024, are as follows (in thousands):

Deferred tax assets:	**December 31, 2025**	**December 31, 2024**
Net operating losses	$ 14,906	$ 8,121
Capitalized research and development	8,521	11,454
Accruals	1	436
Stock-based compensation	1,144	413
Tax credits	4,870	2,696
Leases	760	815
Gross deferred tax assets	**30,202**	**23,935**
Valuation allowance	(29,671)	(23,390)
Total deferred tax assets	**531**	**545**
Deferred tax liabilities:		
Depreciable asset basis differences	(38)	(15)
Unrealized gain - other comprehensive income	(35)	(24)
Operating lease right-of-use assets	(458)	(506)
Total deferred tax liabilities	**(531)**	**(545)**
Net deferred tax assets	**$ —**	**$ —**

The Company's accounting for deferred taxes involves the evaluation of a number of factors concerning the realizability of its net deferred tax assets. The Company primarily considered such factors as its history of operating losses, the nature of the Company's deferred tax assets, and the timing, likelihood and amount, if any, of future taxable income during the periods in which those temporary differences and carryforwards become deductible. As of December 31, 2025 and 2024, the Company does not believe that it is more likely than not that the deferred tax assets will be realized; accordingly, a full valuation allowance has been established and no deferred tax asset is shown in the Company's balance sheets. During the years ended December 31, 2025 and 2024, the valuation allowance increased by $6.3 million and $11.3 million, respectively, which primarily relates to the current year operating loss and capitalized research and development expenses.

On July 4, 2025, new legislation (commonly known as the One Big Beautiful Bill Act or OBBBA) was enacted into law in the United States. The OBBBA includes numerous changes to existing tax law including extending or making permanent certain business and international tax measures initially established under the 2017 Tax Cuts and Jobs Act, which were set to expire. Additionally, the OBBBA permanently eliminates the requirement to capitalize and amortize U.S.-based research and development expenditures over five years and provides the option to make these expenditures fully deductible in the period incurred. The legislation has multiple effective dates, with certain provisions effective in 2025 and others implemented through 2027. The Company does not expect the change to be material to the financial statements due to the Company's full valuation allowance.

The Company believes that income tax filing positions will be sustained upon examination and does not anticipate any adjustments that would result in a material adverse effect on the Company's financial position, results of operations or cash flows. Accordingly, the Company has not recorded any reserves, or related accruals or uncertain income tax positions as of December 31, 2025 and 2024.

The Company recognizes interest accrued related to unrecognized tax benefits and penalties in income tax expense. The Company has no accruals for interest and penalties as of December 31, 2025 and 2024.

The Internal Revenue Code of 1986 contains certain provisions that can limit a taxpayer's ability to utilize net operating loss ("NOL") and tax credit carryforwards in any given year resulting from cumulative changes in ownership interests in excess of 50 percent over a three-year period ("ownership change"). In the event of such a deemed ownership change, Internal Revenue Code Section 382 ("Section 382") imposes an annual limitation on pre-ownership change tax attributes. As of December 31, 2025, the Company has not performed a formal Section 382 study, however the Company has reviewed its temporary deductible differences in conjunction with its temporary taxable differences as a measure against its definite lived net operating losses and anticipates any impact would be immaterial.

As of December 31, 2025, the Company has federal NOL carryforwards of approximately $70.3 million, of which $1.5 million is subject to the 20-year carryforward period and begins to expire in 2036. The remaining federal NOL carryforward of $68.8 million has an indefinite carryforward period.

The Company has available state NOL carryforwards of approximately $41.7 million and $41.9 million as of December 31, 2025 and 2024, respectively. The state NOLs are expected to begin to expire in 2036, although not all states conform to the federal NOL carryforward period and occasionally limit the use of NOLs for a period of time.

As of December 31, 2025, the Company had federal research and development credits of approximately $4.9 million. The research and development credits, if not utilized, will begin to expire in 2036.

The Company is subject to taxation and files income tax returns in the U.S. Federal and state jurisdictions. The statute of limitations for assessment by the Internal Revenue Service and state tax authorities remains open from the tax years December 31, 2021 through December 31, 2025. There are currently no federal or state income tax audits in progress. The tax authorities generally have the ability to review income tax returns for periods where the statute of limitations has previously expired and can subsequently adjust the NOL carryforward or tax credit amounts.

13. Commitments and Contingencies

The Company has contracted with various consultants and third parties to assist in pre-clinical research and development and clinical trials work for the Company's leading drug compounds. The contracts are terminable at any time but obligate the Company to reimburse the providers for any time or costs incurred through the date of termination.

Funding Commitments

In September 2023, the Company entered into a work order with a third-party contract research organization ("CRO") to provide services with respect to the Company's Phase 2 trial of LB-102 for schizophrenia. As of December 31, 2025, the Company has paid all outstanding amounts related to the Phase 2 clinical trial and there are no remaining amounts to be invoiced.

In November 2025, the Company entered into a work order with a third-party to provide clinical trial services with respect to the Company's Phase 3 trial and Open Label. As of December 31, 2025, the Company is committed to fund approximately $0.5 million in advances to the service provider and expects to pay prior to March 31, 2026.

In December 2025, the Company entered into a work order with a third-party CRO to provide services with respect to the Company's Phase 3 clinical trial of LB-102 for schizophrenia ("Phase 3 trial"). As of December 31, 2025, the Company is committed to fund approximately $15.8 million in advances to the CRO and expects to pay prior to March 31, 2026.

In December 2025, the Company entered into a start up work order with a third-party CRO to provide services with respect to the Company's Open Label Safety and Tolerability Study of LB-102 for schizophrenia ("Open Label"). As of December 31, 2025, the Company is committed to fund approximately $11.4 million in advances to the CRO and expects to pay prior to March 31, 2026.

As of December 31, 2025, the Company is committed to fund approximately $1.0 million for various research and manufacturing projects and expects to pay prior to March 31, 2026.

The Company enters into contracts in the normal course of business with contract development and manufacturing organizations ("CDMOs") and other third parties for preclinical research studies and testing and manufacturing services, which are generally cancelable upon prior written notice. Payments due upon cancellation may consist of payments for services provided or expenses incurred, including noncancelable obligations of the Company's service providers, up to the date of cancellation, and may also include termination penalties. As of December 31, 2025 and 2024, the Company had no outstanding liabilities related to such items.

Contingencies

In the normal course of business, the Company is subject to loss contingencies, such as legal proceedings and claims arising out of its business. The Company records accruals for such loss contingencies when it is probable that a liability will be incurred, and the amount of loss can be reasonably estimated. The Company, in accordance with this guidance, does not recognize gain contingencies until realized. The Company is not a party to any litigation and does not have contingency reserves established for any litigation liabilities as of December 31, 2025.

14. Related-Party Transactions

In August 2023, contemporaneously with the closing of the Series C Offering, the Company entered into several amended and restated royalty participation agreements (the "Amended and Restated Royalty Agreements") with certain of its investors, co-founders, former directors, and executive officers, none of whom are Series C New Investors. No consideration was received as part of the Amended and Restated Royalty Agreements. Pursuant to the Amended and Restated Royalty Agreements, the Company is obligated to pay royalties to all of the holders in an aggregate amount up to 2.75% on net sales arising from LB-102 worldwide through December 31, 2035. Thereafter, the Company is obligated to pay royalties to such holders in an aggregate amount up to 3.25% in perpetuity. Net sales are defined in these agreements as the gross payments received on total commercial sales of LB-102 less certain standard deductions, whether received by the Company or any licensee of LB-102. As of December 31, 2025, certain former and current officers of the Company and their affiliates held 1.13% of the future royalties.

15. Subsequent Events

On February 4, 2026, the Company entered into a Securities Purchase Agreement with certain investors pursuant to which the Company, in a private placement, agreed to issue and sell to the investors an aggregate of (i) 3,306,571 shares of the Company's common stock, par value $0.0001 per share and (ii) pre-funded warrants to purchase up to 1,417,107 shares of common stock. Each share was offered and sold at a purchase price of $21.17 before deducting underwriting discounts and commissions and each pre-funded warrant was offered and sold at a purchase price of $21.1699, which is equal to the purchase price per share less the $0.0001 exercise price of each pre-funded warrant, before deducting underwriting discounts and commissions. The Company received gross proceeds of approximately $100.0 million, before deducting any transaction-related expenses. In connection with the private placement, the Company entered into a registration rights agreement pursuant to which it agreed to register the resale of the shares issued in the private placement.