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 001-42914

MapLight Therapeutics, Inc.
(Exact name of Registrant as specified in its Charter)

Delaware	**83-2163243**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
800 Chesapeake Drive Redwood City, California	**94063**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (617) 984-6300

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Voting Common Stock, $0.0001 par value per share	MPLT	Nasdaq Global Select Market

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

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

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 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 equity held by non-affiliates as of such date.

The number of shares of Registrant's Voting Common Stock outstanding as of March 19, 2026 was 42,436,326.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's definitive proxy statement relating to the 2026 Annual Meeting of Stockholders, which will be filed with the Securities and Exchange Commission within 120 days after the end of the Registrant's fiscal year ended December 31, 2025, are incorporated by reference into Part III of this Annual Report on Form 10-K.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K ("Annual Report") contains forward-looking statements that involve substantial risks and uncertainties. The forward-looking statements are contained principally in the sections titled "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations," "Business" and elsewhere in this Annual Report. In some cases, you can identify forward-looking statements by terms such as "anticipate," "believe," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "will," or "would" or the negative of these terms or other similar expressions intended to identify statements about the future. These statements speak only as of the date of this Annual Report and involve known and unknown risks, uncertainties and other important 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 the forward-looking statements. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements include statements about the following:

- the timing, progress and results of our preclinical studies and clinical trials of our product candidates, including statements regarding the timing of initiation and completion of studies or trials and related preparatory work, and the period during which the results of the trials will become available;
- the timing of any regulatory submissions, initiation of and enrollment in clinical trials and timing of expected clinical results for our product candidates;
- our ability to identify patients with the conditions treated by our product candidates and to enroll patients in trials;
- our expectations regarding the size of the patient populations, market acceptance and opportunity for and clinical utility of our product candidates, if approved for commercial use;
- our manufacturing capabilities and strategy, including the scalability and commercial viability of our manufacturing methods and processes;
- our expectations regarding the scope of any potential indications for our product candidates;
- our ability to successfully receive regulatory approval for, and commercialize, our product candidates;
- our ability to identify and develop future product candidates;
- our ability to obtain additional capital and the sufficiency of our existing cash, cash equivalents and investments to fund our future operating expenses and capital expenditure requirements;
- our ability to establish or maintain collaborations or strategic relationships;
- our ability to identify, recruit and retain key personnel;
- our ability to protect and enforce our intellectual property position for our product candidates, and the scope of such protection;
- our financial performance;
- our anticipated use of our existing cash, cash equivalents and investments;
- the impact of laws and regulations; and
- our expectations regarding the time during which we will be an emerging growth company under the JOBS Act.

The foregoing list of risks is not exhaustive. Other sections of this Annual Report may include additional factors that could harm our business and financial performance. Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties. As a result of these factors, we cannot assure you that the forward-looking statements in this Annual Report will prove to be accurate. Except as required by applicable law, we do not plan to

publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise. You should, however, review the factors and risks and other information we describe in the reports we will file from time to time with the SEC after the date of this Annual Report.

Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. Although we believe that we have a reasonable basis for each forward-looking statement contained in this Annual Report, the events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. You should refer to the section titled "Risk Factors" of this Annual Report for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. You should read this Annual Report and the documents that we reference in this Annual Report and have filed as exhibits to the registration statement, of which this Annual Report is a part, completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.

SUMMARY RISK FACTORS

Our business is subject to a number of risks of which investors should be aware before making an investment decision. These risks are discussed more fully in Part I, Item 1A. "Risk Factors" in this Annual Report. These risks include 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, development and future commercialization of product candidates and the prospects for our future viability.
- We will require substantial additional capital to achieve our goals, and failure to obtain additional capital when needed or on acceptable terms, could cause us to delay, limit, reduce or terminate our product development or future commercialization efforts.
- Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.
- Clinical development is a lengthy and expensive process characterized by uncertain outcomes, with results of earlier studies and trials often failing to predict future trial results or results in other indications of a product candidate. We may incur additional costs or experience delays in completing, or fail to complete, the development and commercialization of our current or future product candidates.
- Delays or difficulties in the enrollment and dosing of patients in clinical trials may delay or prevent receipt of necessary regulatory approvals.
- Any significant adverse events or undesirable side effects caused by our product candidates may delay or prevent regulatory approval or market acceptance of our product candidates, or result in significant negative consequences following marketing approval, if any.
- We face potential competition from many different sources, including pharmaceutical and biotechnology companies, academic institutions and governmental agencies, as well as public and private research institutions.
- We may not realize the benefits of our current or future collaborations or licensing arrangements and may be unsuccessful in consummating future partnerships.
- Even if we complete the necessary clinical trials, we cannot predict when, or if, we will obtain regulatory approval to commercialize any product candidate in the U.S. or any other jurisdiction, and any such approval may be for a narrower indication than we seek.
- We are highly dependent on the management, clinical, research and development, manufacturing, financial and business development expertise of our executive officers, and if we are not able to retain

these individuals or recruit additional management or clinical and scientific personnel, our business will suffer.

- We expect to expand our clinical development, manufacturing and regulatory capabilities and potentially implement sales, marketing and distribution capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.
- The manufacturing of our product candidates is complex, and our third-party manufacturers may encounter difficulties in production. If our third-party manufacturers encounter such difficulties, our ability to provide supply of our product candidates for clinical trials, our ability to obtain marketing approval, or provide commercial supply of our products, if approved, could be delayed or halted.
- If we are unable to obtain and maintain sufficient intellectual property protection for our current or future product candidates or if the scope of the intellectual property protection we currently have or obtain in the future is not sufficiently broad, our competitors could develop and commercialize product candidates similar or identical to ours, and our ability to successfully commercialize our current or future product candidates may be impaired.
- We rely on third parties to supply and manufacture our product candidates, and we expect to continue to rely on third parties to manufacture our products, if approved. The development of such product candidates and the commercialization of any products, if approved, could be stopped, delayed or made less profitable if any such third party fails to provide us with sufficient quantities of product candidates or products or fails to do so at acceptable quality levels or prices or fails to maintain or achieve satisfactory regulatory compliance. Furthermore, our reliance on third parties, such as manufacturers, may subject us to risks relating to manufacturing scale-up, which may cause us to undertake substantial obligations, including financial obligations.
- Our suppliers are often subject to strict manufacturing requirements and rigorous testing requirements, which could limit or delay production.
- An active and liquid trading market for our common stock may not be sustained.
- The market price of our common stock may be volatile, which could result in substantial losses for investors.

If we are unable to adequately address these and other risks we face, our business, results of operations, financial condition and prospects may be harmed.

PART I

Item 1. Business.

Overview

We are a clinical-stage biopharmaceutical company focused on improving the lives of patients suffering from debilitating central nervous system, or CNS, disorders. We were founded by globally recognized leaders in psychiatry and neuroscience research to address the lack of circuit-specific pharmacotherapies available for patients. Our discovery platform holds the potential to fill this void by identifying neural circuits causally linked to disease and targeting those circuits for therapeutic modulation. We believe our deep understanding of these causal links between the modulation of defined neural circuits and the resulting changes in disease-specific behaviors will enable us to develop therapeutics that can deliver efficacy, safety, tolerability and ease-of-use advantages to patients and prescribers.

Our lead product candidate, ML-007C-MA, is a fixed-dose combination of an M_1/M_4 muscarinic agonist, ML-007, co-formulated with a peripherally acting anticholinergic, or PAC, which we are initially developing for the treatment of schizophrenia and Alzheimer's disease psychosis, or ADP. ML-007C-MA is designed to activate both M_1 and M_4 muscarinic receptors centrally to drive efficacy, while synchronizing the pharmacokinetics of the agonist and antagonist components to mitigate peripheral cholinergic side effects. ML-007 alone, co-administered, or co-formulated with PAC has been evaluated in four Phase 1 trials, with a total of 270 healthy participants enrolled and more than 1,500 doses of ML-007 administered. Based on our clinical and preclinical data, we believe that ML-007C-MA has demonstrated the potential to be a well-tolerated treatment option with convenient dosing, while achieving or exceeding cerebrospinal fluid, or CSF, exposures expected to result in improvement across key symptom domains. We are conducting ZEPHYR, a Phase 2 trial evaluating ML-007C-MA for the treatment of schizophrenia, and we expect the trial to reach the target enrollment of 300 participants in April 2026 and report topline results in the third quarter of 2026. We are also conducting VISTA, a Phase 2 trial evaluating ML-007C-MA for the treatment of ADP, and expect to report topline results in the second half of 2027. In December 2025, ML-007C-MA was granted Fast Track designation by the FDA for the treatment of hallucinations and delusions associated with ADP.

There remains a significant unmet need in both schizophrenia and ADP for medicines that can effectively treat the breadth of symptoms while reducing the significant safety and tolerability risks for patients. Schizophrenia is a complex psychiatric disorder characterized by a range of symptoms that include positive symptoms of hallucinations, delusions, and disorganized thinking; negative symptoms of social withdrawal, decreased emotional expression, anhedonia, and apathy; and cognitive impairment. Schizophrenia is one of the most common psychotic disorders and affects over 20 million people globally, including more than 3 million people in the United States. Schizophrenia remains one of the leading causes of disability and is associated with an increased risk for premature mortality. Atypical antipsychotics represent the current standard of care and primarily exert their therapeutic effects by binding to and inhibiting the activity of dopamine D_2 receptors in the brain. These dopaminergic antipsychotics are associated with risk of highly morbid side effects of extra pyramidal symptoms, or EPS, (e.g., dystonia, akathisia, tardive dyskinesia), metabolic abnormalities (e.g., weight gain, dyslipidemia, hyperglycemia), hyperprolactinemia, QTc prolongation and sedation. Furthermore, these medications are approved by the FDA only for the treatment of the positive symptoms of schizophrenia and do not address the negative or cognitive symptoms. Meta-analyses of real-world usage of dopaminergic antipsychotics have shown poor treatment adherence and high discontinuation rates due to lack of efficacy and/or undesirable side effects.

ADP represents another significant unmet need, as approximately 40% of the approximately 7 million people in the United States living with Alzheimer's disease also experience symptoms of psychosis. These symptoms are associated with a worsened prognosis and are predictive of earlier progression to nursing home care, severe dementia and death. There are currently no therapies approved for the treatment of ADP, although there is widespread use of off-label dopaminergic antipsychotics. However, based on a meta-analysis, the efficacy of these medications for ADP was shown to be modest at best. Furthermore, dopaminergic antipsychotics are associated with significant side effects, including EPS, metabolic syndrome, cerebrovascular accidents, falls and increased mortality risk in elderly patients with dementia-related psychosis.

We believe targeting muscarinic receptors represents a compelling therapeutic alternative to dopaminergic antipsychotics for the treatment of schizophrenia and ADP. Muscarinic receptors are localized to brain circuits known to be critical for psychosis and cognition, and alterations in muscarinic receptor binding have been observed in post-mortem brain tissue from schizophrenia and Alzheimer's disease patients. The FDA approval of Cobenfy, an M_1/M_4 muscarinic agonist, represents the first product with a novel mechanism approved for the treatment of schizophrenia in decades. Muscarinic receptor-targeted approaches have shown improvements in both positive and negative symptoms of schizophrenia, as demonstrated in multiple randomized controlled clinical trials conducted by third parties. Additionally, in these trials and other open-label extension trials, muscarinic agonists were shown not to cause the serious side effects of EPS and metabolic disturbance associated with dopaminergic antipsychotics.

However, some of these same clinical trials have also demonstrated a high rate of both pro- and anticholinergic side effects, which we believe are caused by a mismatch of agonist and antagonist exposures in the periphery. To mitigate these cholinergic side effects, certain muscarinic agonists have required inconvenient dosing regimens (frequency, titration and fasting requirements) that are likely to result in patient compliance and adherence challenges. Furthermore, although exploratory analyses in these trials suggested a positive effect on cognition symptoms in patients with baseline cognitive impairment, these analyses were not adequately powered to assess statistical significance. These findings suggest that despite the approval of a first agent within the new muscarinic class, there remains a significant opportunity for improvement across efficacy, safety and tolerability, and ease of use.

Based on the results of our Phase 1 Study 013, we believe ML-007C-MA has demonstrated the potential to be a well-tolerated treatment option with convenient dosing, while achieving or exceeding CSF exposures expected to result in improvement across key symptom domains. Study 013 evaluated the safety, tolerability and pharmacokinetics, or PK, of ML-007C-MA in healthy adult and elderly participants that were dosed for up to 14 days. ML-007C-MA was generally well tolerated at the doses being evaluated in our ongoing Phase 2 trials. Most treatment-emergent adverse events, or TEAEs, were mild, self-limited and transient in nature. The mean plasma concentration ratio of ML-007 and PAC remained within the target range established to minimize adverse events over the majority of the dosing interval. ML-007C-MA also achieved and maintained CSF exposures above the anticipated clinically relevant levels with both once- and twice-daily dosing regimens. Based on the PK parameters observed in fasted and fed states, ML-007C-MA will not require administration in a fasted state. Together, the safety and PK observations supported advancing ML-007C-MA to Phase 2 trials in both adult and elderly participants.

Our second product candidate, ML-004, is a $5\text{-HT}_{1B/1D}$ agonist that we are developing for the treatment of social communication deficit and/or irritability in autism spectrum disorder, or ASD. Historical clinical development efforts for ASD have been challenging given the biological heterogeneity of symptoms across age, developmental level and sex, and the lack of validated outcome measures. There are currently no FDA-approved therapies for the core symptoms of ASD, social communication deficit and repetitive/restricted behavior. The only two therapies approved for ASD-associated irritability are atypical antipsychotics, which are associated with serious side effects. ML-004 is an immediate-release, or IR, and extended-release, or ER, formulation of zolmitriptan. We are currently conducting IRIS, a Phase 2 trial to evaluate the efficacy of ML-004 for the improvement of social communication deficits in patients with ASD. Change from baseline in irritability symptoms is a secondary endpoint. We have completed enrollment in this trial and expect to report topline results in the third quarter of 2026. Based on the results from the IRIS trial, we intend to explore potential strategies for further development of ML-004.

In addition, we are advancing multiple preclinical programs, including ML-009, ML-055 and ML-021.

- ML-009 is our G-protein-coupled receptor 52 positive allosteric modulator, or GPR52 PAM, program for the treatment of hyperactivity, impulsivity and agitation-related disorders. We have nominated a preclinical candidate for further advancement and expect to complete investigational new drug application, or IND, -enabling studies in 2027.
- ML-055 is our next-generation, novel M_1/M_4 muscarinic agonist program, which we are developing for the treatment of neuropsychiatric conditions. Preclinical in vitro and in vivo studies evaluating multiple potential candidates have demonstrated significantly greater potency relative to ML-007 and the potential for once-daily dosing and long-acting injectable formulation. We expect to nominate a preclinical candidate to advance to IND-enabling studies in 2026.

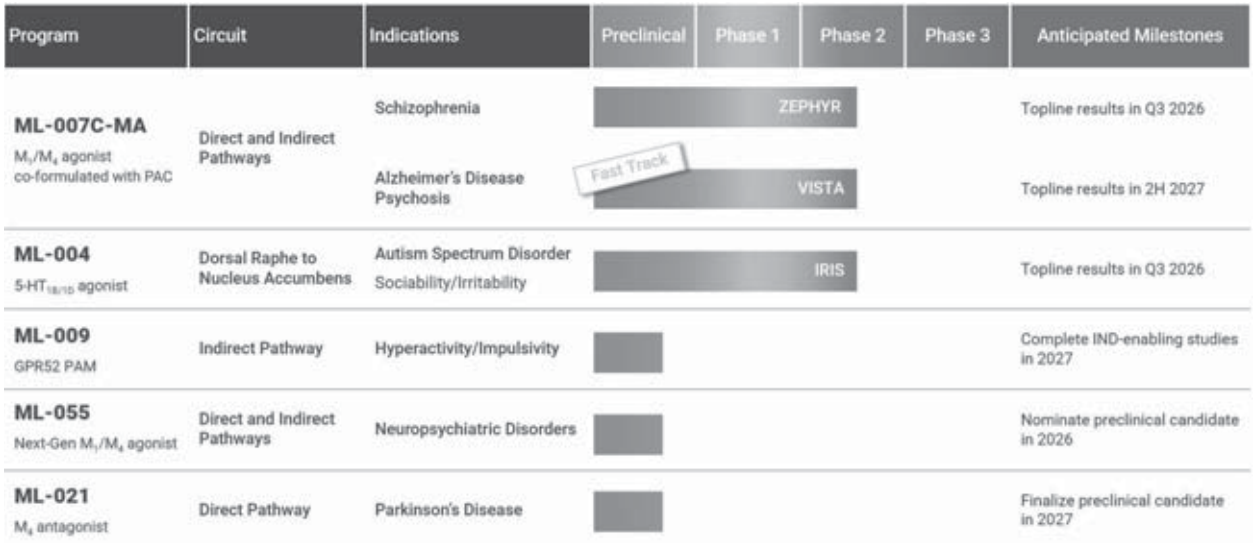
- ML-021 is our M_4 antagonist program for the treatment of motor deficits in Parkinson's disease. We have conducted preclinical studies using multiple potential candidates, including our lead preclinical candidate, and expect to finalize a preclinical candidate to advance to IND-enabling studies in 2027.

Our current and future pipeline is supported by our platform, which is built on our deep understanding of neural circuits that perform specific functions in the brain. We leverage our platform technologies to define how the activity of specific neural circuits is causally linked to disease symptoms and then identify druggable targets within those circuits that correct aberrant circuit activity. Utilizing this approach, we are advancing a robust pipeline of product candidates for the treatment of highly prevalent CNS conditions that collectively afflict millions of people and impose substantial disease burden and costs on patients, families, caregivers and society.

Our Pipeline of Product Candidates

Our pipeline of product candidates is diversified by mechanism and neural circuit to address a breadth of debilitating CNS disorders, and we currently retain global development and commercial rights to all programs.

Figure 1. MapLight Therapeutics Pipeline



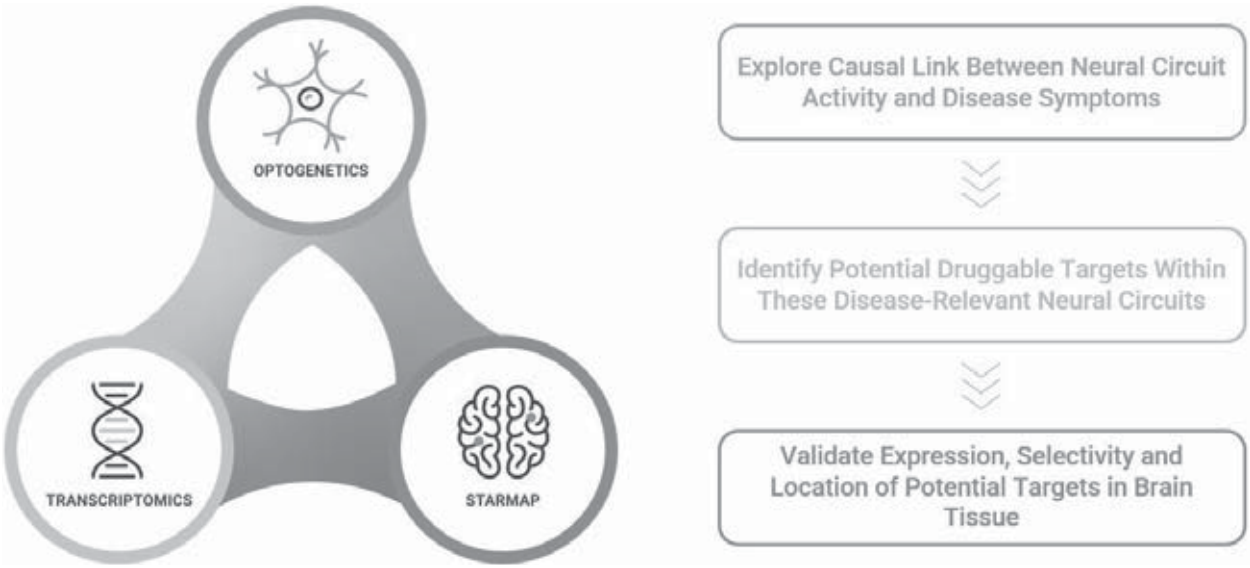
Our Approach and Platform

We were founded by globally recognized leaders in psychiatry and neuroscience research to fill a void in CNS drug discovery by building a platform to identify disease-related neural circuits and target them for therapeutic modulation. Our differentiated approach is based on our deep understanding of the causal links between the modulation of defined neural circuits and the resulting changes in disease-specific behaviors. Our platform consists of three key technologies: optogenetics, a technique that uses light to probe the function of specific neural circuits in the living brain; single cell transcriptomics, a high-throughput technology that isolates single cells from a tissue and then reads out gene expression levels in different cell types; and STARmap, a spatial transcriptomics technology that allows for the visualization of gene expression in neural circuits within preserved slices of brain tissue. We use optogenetics to identify how aberrant activity in a defined neural circuit can cause disease symptoms. Once we have identified a circuit of interest, we employ single-cell transcriptomics and STARmap to identify and spatially localize druggable targets that are selectively expressed within those circuits. We then apply our expertise in medicinal chemistry and drug formulation to identify product candidates that engage the identified targets to ameliorate dysfunctional circuit activity.

We believe this approach holds the potential to generate compelling pipeline opportunities by validating promising targets earlier in the discovery and development process. The multiple, synergistic technologies comprising our platform facilitate our efforts to discover potential product candidates with the optimal combination

of specificity, activity and safety. We believe that our circuit-based discovery strategy will enable us to deliver additional novel and differentiated pipeline programs.

Figure 2. MapLight Therapeutics Discovery Platform



Our Programs

ML-007C-MA for the Treatment of Schizophrenia and Alzheimer's Disease Psychosis

Our lead product candidate, ML-007C-MA, is a fixed-dose combination of an M_1/M_4 muscarinic agonist, ML-007, co-formulated with a PAC, which we are initially developing for the treatment of schizophrenia and ADP. ML-007C-MA is designed to activate both M_1 and M_4 muscarinic receptors centrally to drive efficacy, while synchronizing the pharmacokinetics of the agonist and antagonist components to mitigate peripheral cholinergic side effects. ML-007 alone, co-administered, or co-formulated with PAC has been evaluated in four Phase 1 trials, with a total of 270 healthy participants enrolled and more than 1,500 doses of ML-007 administered. Based on our clinical and preclinical data, we believe that ML-007C-MA has demonstrated the potential to be a well-tolerated treatment option with convenient dosing, while achieving or exceeding CSF exposures expected to result in improvements across key symptom domains. We are conducting ZEPHYR, a Phase 2 trial evaluating ML-007C-MA for the treatment of schizophrenia, and we expect the trial to reach the target enrollment of 300 participants in April 2026 and report topline results in the third quarter of 2026. We are also conducting VISTA, a Phase 2 trial evaluating ML-007C-MA for the treatment of ADP, and expect to report topline results in the second half of 2027. In December 2025, ML-007C-MA was granted Fast Track designation by the FDA for the treatment of hallucinations and delusions associated with ADP.

Overview of Schizophrenia

Schizophrenia is a complex psychiatric disorder characterized by a range of symptoms that include positive symptoms of hallucinations, delusions and disorganized thinking; negative symptoms of social withdrawal, decreased emotional expression, anhedonia and apathy; and cognitive impairment, including attention, memory and executive function deficits. Schizophrenia has a highly variable clinical course characterized by continuous or relapsing episodes of psychosis and hospitalizations, and outcomes range from complete recovery to long-term severe disability. The underlying causes of schizophrenia remain elusive, but the disorder is believed to arise from a combination of genetic, environmental and neurobiological factors. Psychotic features of schizophrenia typically emerge in adolescence or early adulthood, and life expectancy following diagnosis is substantially reduced relative to the general population. Schizophrenia is one of the most common psychotic disorders and affects over 20 million people globally, including more than 3 million people in the United States.

Atypical antipsychotics represent the current standard of care and primarily exert their therapeutic effects by inhibiting the activity of dopamine D_2 receptors in the brain, though most also interact with other receptors (e.g., serotonin, histamine and adrenergic receptors). These dopaminergic antipsychotics are associated with significant side effects, including the risk of serious movement disorders (e.g., tardive dyskinesia, akathisia, dystonia), metabolic abnormalities (e.g., weight gain, dyslipidemia, hyperglycemia), hyperprolactinemia, QTc prolongation and sedation. Furthermore, these medications are approved by the FDA only for the treatment of the positive symptoms of schizophrenia and do not address the negative symptoms nor cognitive impairment. It is estimated that approximately 30% of patients have no response to treatment and an estimated 30 to 60% of patients only have a partial or inadequate response to dopaminergic antipsychotics. A large meta-analysis of real-world usage of commonly prescribed dopaminergic antipsychotics showed that approximately 74% of patients discontinued treatment within 18 months due to undesirable side effects or lack of efficacy. There is an urgent unmet medical need for safe and effective new treatments that address the entire spectrum of symptoms associated with schizophrenia.

Overview of Alzheimer's Disease Psychosis

Alzheimer's disease, or AD, is a progressive and chronic neurodegenerative disease defined by memory and cognitive deterioration beyond normal aging that becomes severe enough to interfere with daily tasks. It is characterized by the loss of neurons and synapses in the cerebral cortex and certain subcortical regions. Neuropsychiatric symptoms and disorders are frequently observed with most patients living with AD. Psychotic symptoms, which are characterized by the presence of delusions and/or hallucinations, occur in approximately 40% of people with Alzheimer's disease at some point during their illness and their likelihood increases as the disease progresses. Psychotic symptoms are associated with poorer disease outcomes, including high rates of institutionalization, more rapid cognitive and functional decline, and increased mortality rates.

There are currently no therapies approved for the treatment of ADP, although there is widespread use of off-label antipsychotics. A large meta-analysis showed that antipsychotics carry a risk of increased mortality in elderly patients with dementia-related psychosis, or DRP, including those with ADP (a subset of DRP). This meta-analysis resulted in the FDA issuance of a boxed warning in the labeling of another product for increased risk of mortality in elderly patients with DRP with antipsychotic usage. Furthermore, dopaminergic antipsychotics are also associated with the risk of serious side effects, including EPS, metabolic syndrome, cerebrovascular accidents, and falls. There is a significant unmet need for effective, safe, and well-tolerated treatments for ADP.

Muscarinic Receptors – Overview and Therapeutic Potential

Muscarinic receptors have emerged as potentially compelling therapeutic targets in recent years for treatment of psychosis and cognitive impairment in several neuropsychiatric disorders, including schizophrenia and ADP. Muscarinic receptors are a family of G protein-coupled receptors that are activated by the neurotransmitter acetylcholine. Muscarinic receptors serve several key physiological roles in cognitive, behavioral, sensory, motor and autonomic processes. There are five subtypes of muscarinic receptors (M_1-M_5), each with distinct regional distributions and functional roles. M_1 and M_4 receptor subtypes show the highest expression in brain where they localize to regions implicated in psychosis and cognitive impairment. Alterations in muscarinic receptors have been observed in post-mortem brain tissue from schizophrenia and Alzheimer's patients.

The therapeutic effect of muscarinic receptor agonism in psychosis is thought to be mediated by M_1 and M_4 receptors in the basal ganglia, prefrontal cortex and hippocampus. In the basal ganglia, the activation of M_1 and M_4 receptors is thought to counterbalance dopamine activity through the direct and indirect pathways, leading to a stronger reliance on external cues to shape reality, thereby reducing delusions, hallucinations and other symptoms of psychosis. In the prefrontal cortex and hippocampus, activation of M_1 receptors is thought to enhance the formation of a coherent and linear set of short- and long-term memories that underpins the perception of a stable reality.

Although activation of M_1 or M_4 alone has shown efficacy in animal models of psychosis at high doses, targeting both M_1 and M_4 is considered to be important for achieving meaningful efficacy in these models at clinically relevant doses. Targeting both M_1 and M_4 receptors is predicted to regulate basal ganglia circuitry synergistically and more effectively than either receptor alone. Together, these multifaceted actions of muscarinic agonists offer the potential of treating psychosis without relying on direct dopamine receptor blockade, the mechanism theorized to drive many of the serious side effects of dopaminergic antipsychotics.

However, muscarinic receptors are also present in various peripheral tissues where acetylcholine plays a role in mediating involuntary muscle movements and glandular secretions. Agonism of peripheral muscarinic receptors could lead to procholinergic side effects, including vomiting, diarrhea, increased salivation and sweating. Despite the promising therapeutic benefit of targeting muscarinic receptors to treat psychosis and related behavioral symptoms in patients with schizophrenia and AD, historical efforts to develop muscarinic agonists have been challenged by the inability to achieve sufficient CNS exposures for efficacy without accompanying peripheral cholinergic side effects.

Two different strategies have emerged to reduce the peripheral side effects of muscarinic agonism: (1) combination of the muscarinic agonist with a peripheral antagonist and (2) receptor selectivity without pairing with a peripheral antagonist, each as described below.

M_1/M_4 Muscarinic Agonist Paired with Peripheral Antagonist:

The rationale for combining a M_1/M_4 muscarinic agonist with a peripherally acting muscarinic antagonist is to enable sufficient agonist activity centrally to achieve efficacy while using an antagonist to mitigate peripheral procholinergic side effects.

Cobenfy, also known as KarXT, currently being developed and marketed by Bristol Myers Squibb, is a combination product consisting of xanomeline, an M_1/M_4 muscarinic agonist, co-formulated with the peripherally acting muscarinic antagonist, trospium. Cobenfy represents the first drug with a novel mechanism of action that has been approved by the FDA for the treatment of schizophrenia in decades. Multiple Phase 3 trials for Cobenfy are ongoing or planned for the treatment of ADP, Alzheimer's disease cognition, Alzheimer's disease agitation and bipolar disorder.

In Phase 2 and Phase 3 schizophrenia trials, patients treated with Cobenfy showed a statistically significant and clinically meaningful placebo-adjusted reduction in total PANSS score (both positive and negative symptoms independently) and clinician-rated improvements in symptoms. Furthermore, although exploratory analyses suggested a positive effect on cognition symptoms in patients with baseline cognitive impairment, these analyses were not adequately powered to fully assess statistical effect in these trials. Additionally, in these trials and other open-label extension, or OLE, trials, treatment with Cobenfy did not cause the serious side effects of EPS and metabolic disturbance traditionally associated with dopaminergic antipsychotics.

However, treatment with Cobenfy has been associated with both procholinergic (e.g., diarrhea, vomiting, nausea, hypersalivation, sweating) and anticholinergic (e.g., constipation, dry mouth, tachycardia, urinary retention) side effects. In Phase 1 trials in healthy adult and elderly participants, Cobenfy was associated with high rates of cholinergic adverse events, a meaningful portion of which were moderate adverse events. Similar rates and types of cholinergic adverse events were also reported in Phase 2, Phase 3 and OLE studies for Cobenfy in schizophrenia patients.

Based on Cobenfy's dosing frequency, fasting requirements (taken at least 1 hour before or 2 hours after a meal), and extended titration period, we believe there is significant room for improvement for more convenient treatment options. According to the FDA prescribing label for schizophrenia, Cobenfy is dosed twice daily and requires a 3-8 day titration period. In the currently ongoing Phase 3 ADEPT-2/3/4 studies for ADP, Cobenfy is dosed three times a day and requires a 5-week titration period. Finally, Cobenfy is also contraindicated or not recommended in certain patients with hepatic and renal impairment.

Together, these findings suggest that further optimization is possible to address side effects and improve the therapeutic profile of the muscarinic class. We believe that synchronization of the PK of the agonist and antagonist components of ML-007C-MA could result in mitigation of pro- and anticholinergic side effects, enabling enhanced tolerability and more convenient dosing, while achieving or exceeding CSF exposures expected to result in improvement across key symptom domains.

Receptor Selectivity Approach Without Pairing with Peripheral Antagonist (e.g., M_4-only agonists):

Receptor selective approaches such as those employed by M_4-selective agonists rely on sacrificing efficacy at the M_1 receptors with the goal of reducing some of the peripheral procholinergic side effects. While product

candidates relying on these approaches have demonstrated favorable safety, tolerability and dosing convenience, the efficacy of these programs in large randomized controlled trials has been negative, mixed or remains unknown. In addition, the lack of M_1 activity with these approaches suggests that they would not be expected to address the cognitive symptoms in either schizophrenia or Alzheimer's disease.

Overview of Our Approach

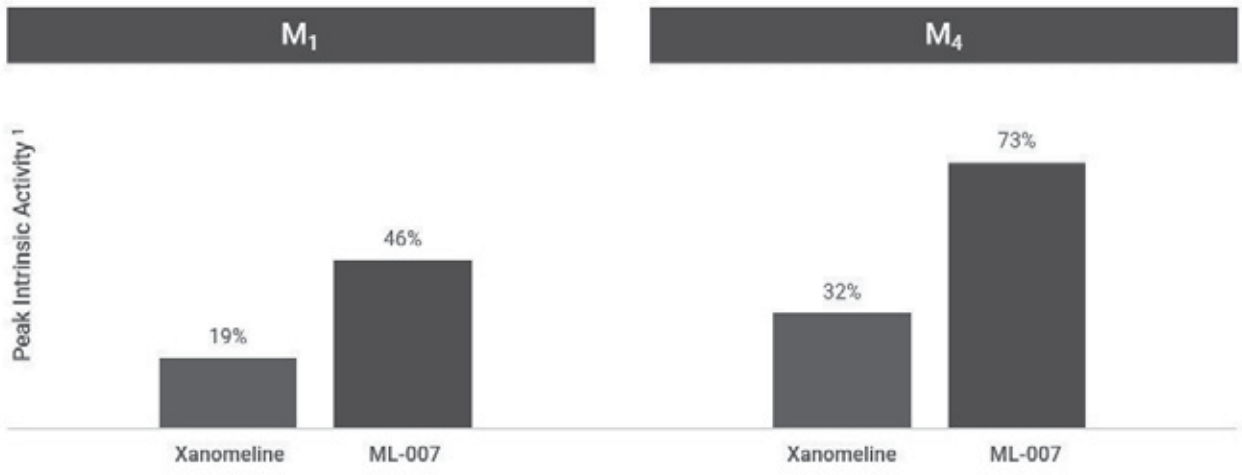
We believe that the combination approach of activating both M_1 and M_4 muscarinic receptors in the CNS, paired with precision-matched antagonism of muscarinic receptors in the periphery, is the key to achieving the optimal therapeutic profile for the muscarinic agonist class. ML-007C-MA is designed to activate both M_1 and M_4 muscarinic receptors centrally to drive efficacy, while synchronizing the pharmacokinetics of the agonist and antagonist components to mitigate peripheral cholinergic side effects.

ML-007 Has Robust Activity at Both M_1 and M_4 Receptors

ML-007 is a brain-penetrant muscarinic M_1/M_4 agonist that has demonstrated strong activation of both M_1 and M_4 receptors across *in vitro* and *in vivo* preclinical studies.

In the GTPgS assay, which measures one of the signaling events proximal to receptor activation, ML-007 was a strong partial agonist at both the M_1 and M_4 receptors. In a head-to-head comparison, ML-007 demonstrated a greater than two-fold higher peak intrinsic activity relative to xanomeline in this assay (see Figure 3). Stronger agonism of ML-007 supports the potential for a wider range of agonist activity, requiring fewer ligand-receptor binding events, lower likelihood of acting as a functional antagonist at high concentrations, and a potential to improve specific symptoms that may require a higher level of activity for physiological response.

Figure 3: Relative Peak Intrinsic Activity at M_1 and M_4 Receptors for ML-007 and Xanomeline



ML-007 has been evaluated in dose-response assays in multiple species and animal models that are predictive of muscarinic receptor activation, including hyperlocomotion, conditioned avoidance response, resident intruder, cognition and dyskinesia models. The pharmacodynamic activity of ML-007 in these animal studies was correlated with CSF exposures to define our target efficacious CSF concentration range of 14 to 27 ng/mL. To validate our target CSF concentration range, we benchmarked the *in vivo* pharmacodynamic activity and CSF exposures of ML-007 and xanomeline in these preclinical models. ML-007 has demonstrated approximately 10-fold greater potency by dose compared to xanomeline, as shown in head-to-head studies across multiple *in vivo* models, including amphetamine-induced hyperlocomotion, phencyclidine-induced hyperlocomotion, and conditioned avoidance response.

The relevance of activity at M_1 and M_4 muscarinic receptors in reducing hyperlocomotion was also established with knockout, or KO, mice in the amphetamine induced hyperlocomotion, or AIH, model for both ML-007 and xanomeline. These studies demonstrated that at clinically relevant doses, greater pharmacodynamic effects are observed with activation of both M_1 and M_4 receptors (wild type) compared to either receptor alone (M_1 or M_4 KO) for both ML-007 and xanomeline. These studies also demonstrated ML-007's robust activity at both M_1 and M_4 receptors. Consistent with its stronger M_1 activity, ML-007 (but not xanomeline) improved both spatial and social memory in a mouse model of Alzheimer's disease.

Favorable Physical / Chemical Properties for Combination Product

ML-007 is highly soluble, is quickly absorbed and distributed throughout the body and has low protein binding. In addition, it has demonstrated high oral bioavailability in animals and is not subject to substantial first-pass metabolism by the liver following absorption in the gastrointestinal tract. These physical and chemical properties have resulted in low inter-patient variability in exposure in clinical trials to date, which has allowed us to optimize the PK synchronization of the two components in the development and formulation of ML-007C-MA.

ML-007 activates muscarinic receptors in the brain, and like other muscarinic agonists, also engages muscarinic receptors in peripheral tissues. Activation of these peripheral receptors produces unwanted procholinergic effects, including nausea, vomiting, diarrhea, hypersalivation and increased sweating. Combining ML-007 with a precision-matched PAC is intended to mitigate these effects, while preserving the desired activity in the brain. To reliably block the peripheral activation of muscarinic receptors, the antagonist must have predictable PK, and its peripheral exposure should match the exposure of the agonist both temporally and quantitatively. Insufficient antagonist activity to neutralize agonist activity results in procholinergic side effects, whereas excessive antagonist activity results in anticholinergic side effects.

We have selected fesoterodine as the PAC component based on its attractive physical and chemical properties (similar to ML-007) and predictable exposures. Fesoterodine is an FDA-approved PAC for the treatment of overactive bladder with symptoms of urinary incontinence, urgency and frequency. The PAC has high solubility (> 50 mg/mL in water), high oral bioavailability, low protein binding, and minimal drug-drug interaction liability. The favorable physical chemical properties of the PAC make it ideal for a combination product to enable precision matching of the PK profiles. In addition, the PAC has demonstrated low CNS permeability compared to other anticholinergics across *in vitro* and *in vivo* studies, which is further confirmed by the low rates of CNS-related AEs relative to placebo reported in prior clinical trials conducted by third parties. The low CNS penetration of the PAC was also confirmed in our dose-escalating animal studies, which demonstrated that plasma ratios of ML-007 to PAC greater than 10:1 resulted in no meaningful inhibition of ML-007's central effects.

Synchronized Agonist / Antagonist Exposures

ML-007 alone, co-administered or co-formulated with PAC has been studied in four completed Phase 1 clinical trials, with 270 healthy participants enrolled and more than 1,500 doses of ML-007 administered. Our deliberate and methodical approach to the Phase 1 clinical development has allowed us to evaluate a broad range of doses and dose ratios of the combination to characterize the impact on safety and tolerability. The fixed dose combination of ML-007C-MA is denoted as dose of ML-007 (in mg) in combination with dose of PAC (in mg) in subsequent sections.

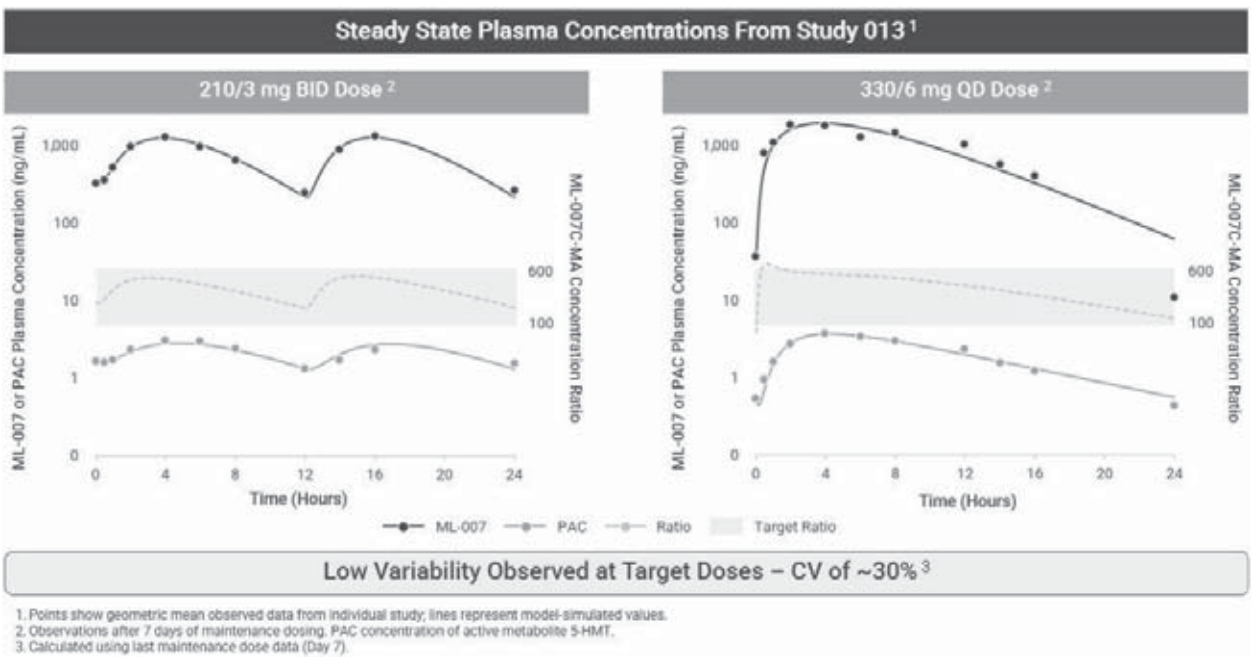
Study 011, which enrolled 13 cohorts and evaluated 22 different dosing paradigms of immediate-release oral solution ML-007 alone and co-administered with oral solution PAC, explored a wide range of dosing ratios to attempt to optimize the peripheral side effect profile of the combination. Pharmacodynamic measures of peripheral muscarinic activity, and in particular salivary volume changes, functioned as real-time markers in the refinement of ratios of ML-007 to PAC. Anticholinergic events (e.g., dry mouth, tachycardia, feeling hot, and dry eye) were most frequently observed at ML-007:PAC plasma exposure ratios less than 100:1, and procholinergic events (e.g., nausea, vomiting, diarrhea, hyperhidrosis, and hypersalivation) were more common at plasma ratios greater than 600:1. Together with an evaluation of tolerability, including cholinergic side effects and objective safety measures (e.g., heart rate, blood pressure and ECG findings), the analyses allowed for establishment of a target plasma ratio of ML-007:PAC of 100:1 to 600:1.

Study 012 evaluated escalating once-daily and twice-daily doses of extended-release ML-007, or ML-007 ER, co-administered with PAC ER at doses and ratios informed by the prior clinical trials. Although the release profiles of the two components were not fully optimized, the study demonstrated close PK synchronization of the two components. The observed and modeled ratio of the plasma concentrations of the two components was tightly matched and remained within the target range throughout the duration of the dosing cycle.

Study 013 evaluated doses up to 210/3 mg twice daily, or BID, and 330/6 mg once daily, or QD, in single and multiple-dose paradigms. This was the first study to utilize the bi-layer, co-formulated tablet of ML-007C-MA, the same formulation that is currently under evaluation in our ongoing Phase 2 trials. The study demonstrated that ML-007C-MA BID and QD target doses at steady state achieved and maintained ML-007 CSF concentrations that exceeded our target range over the majority of the dosing period in both healthy adults and healthy elderly participants. In addition, ML-007:PAC plasma concentration ratios were generally maintained within the target range at steady state (see Figure 4 below) during the dosing period. The PK exposures at the target doses at steady state (Day 7) demonstrated low variability, with a coefficient of variation (CV) of approximately 30%.

For a further description of the design of our Phase 1 clinical trials, see "—ML-007C-MA Clinical Development History" below.

Figure 4: Matching of ML-007 and PAC Plasma Concentrations Demonstrated in Study 013



Potential Advantages of Our Lead Product Candidate, ML-007C-MA

Based on the results of our preclinical and clinical studies to date, we believe that ML-007C-MA has demonstrated the potential to be differentiated across the following key domains:

- **Safety and Tolerability Profile**: Precision matching of the peripheral exposures of the muscarinic agonist, ML-007, and PAC is designed to limit the pro- and anticholinergic side effects. ML-007C-MA was generally well tolerated in healthy adult and elderly participants at the doses being evaluated in the ongoing Phase 2 studies.
- **Ease of Use**: In Study 013, ML-007C-MA was well tolerated with minimal titration and achieved CSF exposures above anticipated clinically relevant levels with once- or twice- daily dosing. The PK parameters in different food states showed that ML-007C-MA administration will not require a fasted state. Our Phase 2 ZEPHYR trial for schizophrenia employs a single titration dose and our Phase 2 VISTA trial for ADP employs a 1-week titration to reach the target maintenance dose.

- **Therapeutic Benefit Across Key Symptom Domains**: We believe that strong activation of both M_1 and M_4 receptors by ML-007C-MA has the potential to improve both positive and negative symptoms of schizophrenia. ML-007C-MA also offers the potential to improve cognitive symptoms based on ML-007's strong M_1 agonism shown in preclinical studies and provide cognitive benefit previously demonstrated by other muscarinic agonists in clinical trials.

Safety and Tolerability Profile

We have performed clinical PK / PD trials of ML-007 and the PAC along with formulation optimization to attempt to precisely match the peripheral exposures of the agonist and antagonist components of ML-007C-MA, which has shown favorable tolerability in healthy adult and elderly participants.

In Study 013, at steady state after multiple BID and QD doses of ML-007C-MA were administered in healthy adults and elderly participants, the plasma ML-007:PAC concentration ratios were generally maintained within the desired range over the dosing interval. In addition, the PK exposures at steady state demonstrated low inter- and intra-subject variability.

ML-007C-MA was generally well tolerated in healthy volunteers at the doses currently being evaluated in the ongoing Phase 2 trials. At these doses:

- Most of the TEAEs observed were mild, transient and self-limiting in nature.
- Low rates of moderate TEAEs were observed, and there were no serious or severe adverse events.
- Most TEAEs were cholinergic in nature, and procholinergic events were reported more frequently than anticholinergic events.
- No clinically meaningful changes in mean blood pressure were observed.
- No clinically meaningful mean changes across any laboratory values, including liver enzyme levels, were observed.

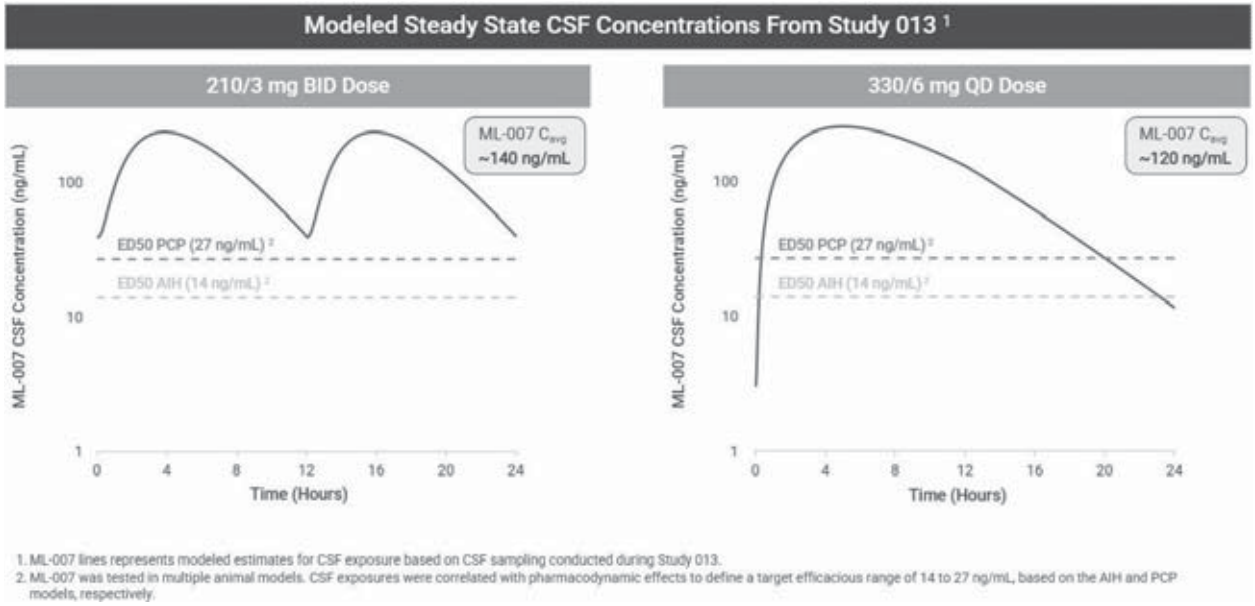
The safety and tolerability profile observed in this trial supported advancing doses up to 210/3 mg BID and 330/6 mg QD for the Phase 2 ZEPHYR trial in schizophrenia and doses up to 210/3 mg BID for the Phase 2 VISTA trial in ADP.

Ease of Use

Once- and Twice-Daily Dosing Expected

Bioanalysis of plasma and CSF samples that were collected throughout our Phase 1 development has allowed us to reliably model the CSF exposures for ML-007 based on plasma PK exposures. PK modeling of the observed plasma and CSF data in Study 013 was used to predict ML-007 CSF concentration profile at steady state for our target doses over the dosing interval. The target doses of 210/3 mg BID and 330/6 mg QD doses resulted in predicted CSF exposures at or above the target range for all or most of the dosing period, as shown in Figure 5.

Figure 5: Modeled CSF Exposures for ML-007 at the Phase 2 Target Doses



Minimal Titration Requirements Expected

We have evaluated a number of titration regimens through our Phase 1 development. In Study 013, the target doses in healthy adults were better tolerated when preceded by a single lower titration dose. In this trial, we also evaluated both a 2- and 7-day titration period in healthy elderly participants, demonstrating that both were tolerable. Our Phase 2 ZEPHYR trial for schizophrenia employs a single titration dose to reach the target maintenance dose for both BID and QD dosing regimens. Our Phase 2 VISTA trial for ADP employs a 1-week titration to reach the target maintenance dose.

No Fasting Requirements Expected

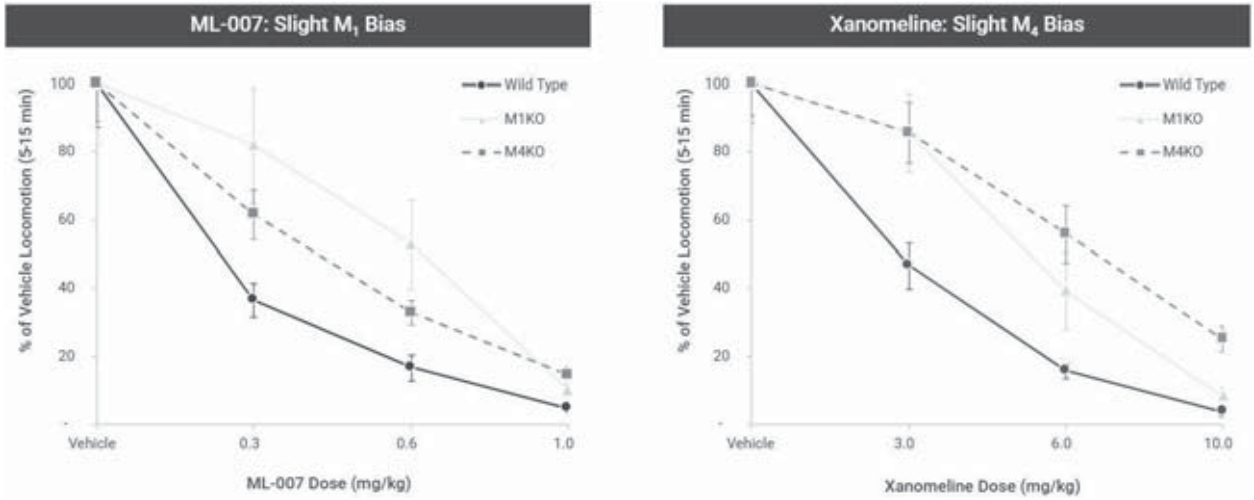
In Study 013, we explored dosing in healthy participants under fasted and fed conditions. ML-007C-MA was well tolerated in fed and fasted conditions, but tolerability was improved when administered in the fed conditions. ML-007 PK exposures were higher in the fed conditions compared with the fasted condition while there was no food effect on the PAC PK. Between low-calorie/low-fat and high-calorie/high-fat conditions, the PK exposures for both ML-007 and PAC were comparable. In the ongoing Phase 2 trials, ML-007C-MA will be dosed proximal to a meal.

Therapeutic Benefit Across Key Symptom Domains

Both M_1 and M_4 Receptors Played Significant Roles in the Reduction of Symptoms in the Amphetamine-Induced Hyperlocomotion Model

Activation of both M_1 and M_4 receptors has been proposed to alleviate psychotic behaviors. To test which receptors contribute to the therapeutic effects of ML-007 and xanomeline in the AIH model, both drugs were evaluated in wild-type M_1 knockout, or M1KO, and M_4 knockout, or M4KO, mice. This study demonstrated that activation of both M_1 and M_4 receptors is required for antipsychotic activity of ML-007 and xanomeline at clinically relevant doses in the AIH model. At high doses, M_1 or M_4 activation by ML-007 was sufficient to reverse hyperlocomotion in the AIH model (see Figure 6). Xanomeline did not reach full activity with M_1 activation alone. Importantly, ML-007 showed a slight M_1 bias whereas xanomeline showed a slight M_4 bias, suggesting that in addition to having strong antipsychotic activity, ML-007 may have additional potential to treat M_1-dependent deficits such as cognition.

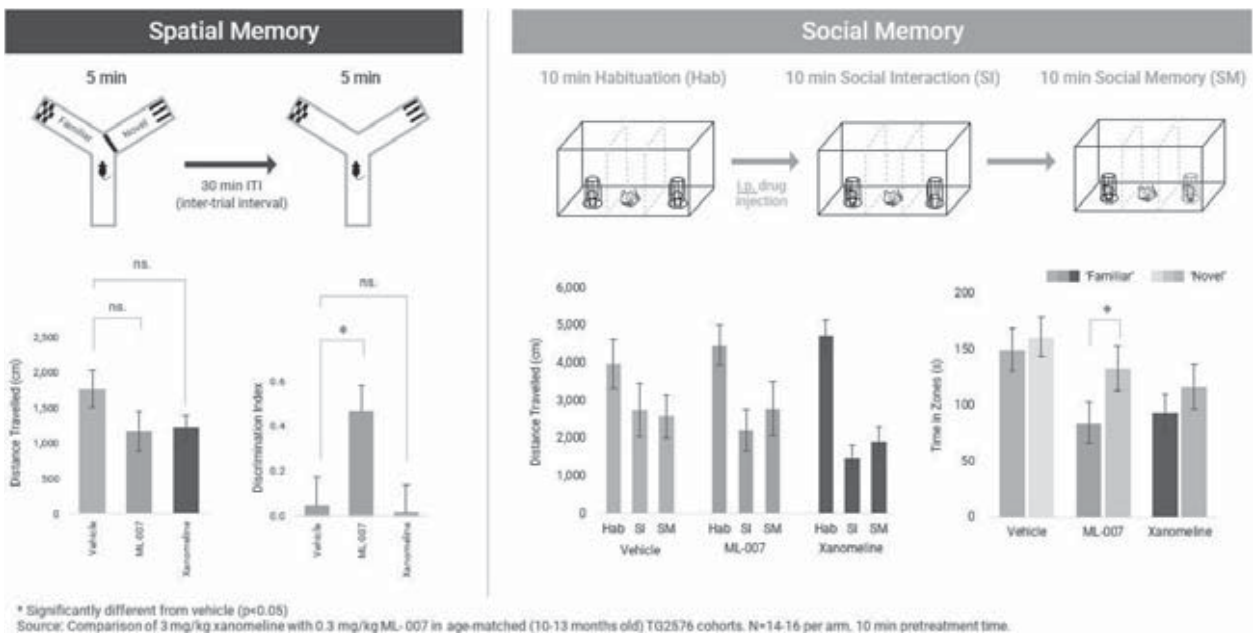
Figure 6: Pharmacodynamic Effects of ML-007 and Xanomeline in WT, M1KO and M4KO AIH Models



ML-007 Improved Memory in a Mouse Model of Alzheimer's Disease

To evaluate the pro-cognitive effects of ML-007 and to compare its activity with xanomeline in a head-to-head study, mice with impaired memory (in a model of Alzheimer's disease) were given each drug separately and assessed in one of two tasks: a Y-maze spatial reference memory assay (see Figure 7, left) or a social memory assay (see Figure 7, right). Equipotent doses of ML-007 and xanomeline were chosen based on their similar effects on locomotion. Treatment with ML-007 significantly improved spatial memory in the Y-maze, improving discrimination between familiar and novel spaces, whereas xanomeline did not improve memory performance. In the social memory test, ML-007, unlike xanomeline, enhanced the memory of a familiar mouse, relative to a novel mouse and the test mouse spent more time with the novel mouse. Taken together, these data support the conclusion that ML-007 exerted pro-cognitive effects in an animal model with memory impairment.

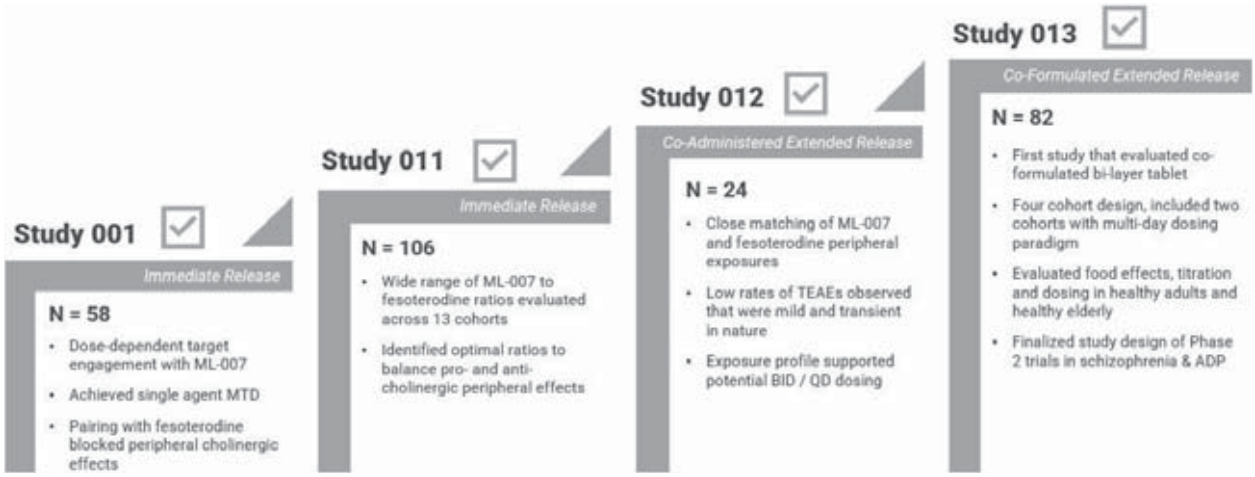
Figure 7: Observed Improved Spatial Memory and Social Memory Following ML-007 Administration



ML-007C-MA Clinical Development History

We have completed four Phase 1 clinical trials with ML-007 alone, co-administered or co-formulated with PAC, with 270 healthy participants enrolled and more than 1,500 doses administered. These trials allowed for the establishment of well-tolerated dosing regimens expected to provide adequate CNS exposure of ML-007 while mitigating the peripheral cholinergic AEs. See Figure 8 below for the Phase 1 development history.

Figure 8: Summary of Phase 1 Clinical Trials



Study 013

Our most-recent Study ML-007C-MA-013, or Study 013, was a single-center Phase 1, 4-cohort study to evaluate the safety, tolerability, and PK of ML-007C-MA under fasted versus fed conditions, with single and multiple doses of ML-007C-MA in healthy adult participants and multiple doses of ML-007C-MA in healthy elderly participants. In addition, this study explored the safety and tolerability of higher doses of ML-007 than previously tested, and whether titration had an impact on safety and tolerability.

- Cohort 1 evaluated a single ML-007C-MA dose of 165/3 mg in 10 healthy adult participants under fasted and fed conditions.
- Cohort 2 evaluated escalating doses of ML-007C-MA up to 210/3 mg BID and 330/6 mg QD in 8 healthy adult participants.
- Cohorts 3 and 4 evaluated ML-007C-MA and placebo in healthy adult (Cohort 3) and healthy elderly (Cohort 4) participants in a multi-dose paradigm with a 7-day treatment at target maintenance doses. In each cohort, 32 participants were enrolled with 8 participants in each dosing group, 2 of whom were randomized to receive placebo.

In Cohort 1, ML-007 PK exposures were higher in the fed conditions compared with that in the fasted condition, while there was no food effect on the PAC PK. Between low-calorie/low-fat and high-calorie/high-fat conditions, the PK exposures for both ML-007 and PAC were comparable. ML-007C-MA was well tolerated in fed and fasted conditions, but tolerability was improved when administered in the fed conditions.

In Cohort 2, ascending doses of up to 210/3 mg BID and 330/6 mg QD were considered safe and well tolerated. Tolerability of 210/3 mg was improved when a single lower titration dose was administered 12 hours prior.

In Cohort 3, maintenance doses of 165/3 mg BID, 210/3 mg BID, 270/6 mg QD, and 330/6 mg QD were evaluated in healthy adult participants. Titration regimens of one dose to four days of dosing were assessed. All four dosing regimens of ML-007C-MA were well tolerated during titration and for the full 7-day maintenance dosing duration. Most TEAEs were mild and no severe or serious TEAEs were observed. Most TEAEs were cholinergic in nature, and procholinergic events were reported more frequently than anticholinergic events. The types of TEAEs,

their incidence and intensity did not worsen with multiple days of dosing. At these doses, the most common non-procedural TEAEs (occurring in more than one participant in any ML-007C-MA group and at a greater incidence than placebo) during maintenance dosing were chills, constipation, dizziness, dyspepsia, headache, hyperhidrosis, nausea, salivary hypersecretion, and vomiting.

At the target doses selected for the ongoing Phase 2 ZEPHYR trial in schizophrenia, the most common non-procedural TEAEs (occurring in more than 1 participant in any ML-007C-MA group and at a greater incidence than placebo) during maintenance dosing are shown in Figure 9. At these target doses during the maintenance dosing period, no episodes of vomiting or constipation were reported. In addition, there were no episodes of anticholinergic TEAEs.

Figure 9: Summary of TEAEs Observed in >1 Participant During the 7-Day Maintenance Dose Period at Target Doses Selected for Ongoing Phase 2 ZEPHYR Trial in Schizophrenia

	Placebo Combined (N = 8) [2]	210/3 mg BID (N = 6)	330/6 mg QD (N = 6) [3]
Subjects with Any TEAE [1]	2 (25%)	3 (50%)	4 (67%)
Mild	2 (25%)	3 (50%)	4 (67%)
Moderate [3]	0 (0%)	1 (17%)	2 (33%)
Severe	0	0	0
Most Common TEAEs (>1 Subject in any Dose Group)			
Chills	0	0	2 (33%)
Hyperhidrosis	0	1 (17%)	2 (33%)
Nausea	0	3 (50%)	3 (50%)
Dizziness	0	3 (50%)	2 (33%)
Dyspepsia	0	0	2 (33%)

1. AEs include events occurring after administration of target dose until 24 hours after last dose. Procedural AEs are excluded. Reported as N (%).
2. Placebo arm reported three AEs, including two episodes of headache and one episode of increased heart rate.
3. One 330/6 mg participant discontinued dosing due to AEs.

In Cohort 4, maintenance doses of 165/3 mg BID, 210/3 mg BID and 330/6 mg QD were evaluated in healthy elderly participants. Titration regimens of 2 days and 7 days were assessed. The titration dose of 105/1.5 mg BID and maintenance doses of 165/3 mg BID and 210/3 mg BID were well tolerated. However, the maintenance dose of 330/6 mg QD was not well tolerated. Most TEAEs across the cohort were mild and there were no severe or serious TEAEs. Most TEAEs were cholinergic in nature, and procholinergic events were reported more frequently than anticholinergic events.

In healthy elderly participants who received BID dosing regimens up to 210/3 mg, the most frequently reported non-procedural TEAEs (occurring in more than one participant in any ML-007C-MA BID group and at a greater incidence than placebo) during maintenance dosing were abnormal feces, hyperhidrosis, nausea, feeling hot, upper abdominal pain, dizziness, headache, penile burning sensation, and tremor. In elderly adults who received QD 330/6 mg, which was not considered well tolerated, the most frequently reported non-procedural TEAEs during maintenance dosing were nausea, dizziness, headache, tremor, hyperhidrosis, salivary hypersecretion, vomiting, chills, fatigue, malaise, increased blood pressure and decreased appetite.

At the target dose selected for the ongoing Phase 2 trial in ADP, the most common non-procedural TEAEs (occurring in more than one participant in any ML-007C-MA group and at a greater incidence than placebo) during maintenance dosing are shown in Figure 10. At the target dose during the maintenance dosing period, only one episode of vomiting and one episode of constipation were reported. In addition, there were low rates of anticholinergic TEAEs, including no episodes of urinary retention.

Figure 10: Summary of TEAEs Observed in >2 Participants During the 7-Day Maintenance Dose Period at Target Dose Selected for Ongoing Phase 2 VISTA Trial in ADP

	Placebo Combined N = 7 [2]	210/3 mg BID (with 2-7d titration) N = 11 [2]
Subjects with Any TEAE [1]	5 (71%)	8 (73%)
Mild	5 (71%)	8 (73%)
Moderate	0	2 (18%)
Severe	0	0
Most Common TEAEs (>2 Subjects)		
Hyperhidrosis	0	3 (27%)
Nausea	0	3 (27%)
Dizziness	1 (14%)	3 (27%)
Headache	0	4 (36%)
Tremor	0	3 (27%)

1. AEs include events occurring after administration of target dose until 24 hours after last dose. Procedural AEs are excluded. Reported as N (%).
2. Two participants discontinued study drug (placebo) due to AEs. Two participants on 210/3 mg BID dose reduced to 165/3 mg BID after experiencing AEs.

Transient dose-dependent mean increases in heart rate, or HR, were observed with ML 007C-MA. However, the magnitude of the increase was generally smaller in elderly adults relative to non-elderly adults. Increased HR has been previously reported for the PAC as a single agent or in other muscarinic agonist programs. There were no clinically meaningful mean changes across any laboratory values. There were no other clinically meaningful changes in vital signs and physical examination findings.

Across all cohorts, the PK of ML-007 and PAC were approximately linear and the PK exposure was not affected by different dose combinations. The steady-state ML-007:PAC concentration ratios after multiple repeated BID or QD dosing generally remained within the desired range of 100:1 to 600:1 over the majority of the dosing interval. In addition, the ML-007 CSF concentration was maintained at or above the predicted efficacious CSF levels as defined by preclinical studies. As a result, we determined the safety and PK observations in ML-007C-MA supported advancing target doses in Phase 2 studies of up to 210/3 mg BID and 330/6 mg QD in non-elderly adult participants and target doses of up to 210/3 mg BID in elderly participants.

Additional Previous Phase 1 Trials

Study 001

Study ML-007-001, or Study 001, was a randomized, placebo-controlled Phase 1 first-in-human, single-ascending dose, or SAD, trial that evaluated the PK, safety and tolerability of ML-007 oral solution in 58 healthy adult participants across two groups.

- Group 1 received ML-007 only, with cohorts receiving escalating single doses (0.8 mg, 2.5 mg, 8.2 mg, 16 mg, 32 mg and 49 mg) until a maximum tolerated dose, or MTD, was reached.
- Group 2 received 6 mg PAC ER or matched placebo administered 4 hours before 32 mg ML-007 (in an effort to match the T_{max} of the two drugs).

The resulting data indicated that ML-007 was generally well tolerated when administered alone up to the MTD of 32 mg. At the ML-007 dose of 32 mg, a CSF concentration of 50 ng/mL was reached around the time of C_{max}, which exceeded the target-estimated, minimum-efficacious CSF level of 20 ng/mL based on animal studies. Data from Group 2 indicated that predosing with 6 mg of PAC reduced procholinergic effects and improved the tolerability of a single dose of ML-007.

Study 011

Study ML-007-011, or Study 011, was a Phase 1 randomized, three-part SAD/multiple ascending dose, or MAD, trial evaluating the safety, tolerability and PK of ML-007 (oral solution) with and without PAC (oral solution) in 106 healthy adults and elderly adult participants.

The three-part trial was designed to evaluate the relative dose and timing of PAC co-treatment required to ameliorate ML-007-associated cholinergic effects in healthy adult participants (Part 1); to evaluate the multiple-dose safety and tolerability of ML-007 oral solution in combination with PAC oral solution in healthy adult participants (Part 2); and to evaluate the multiple-dose safety and tolerability of ML-007 oral solution in combination with PAC oral solution in healthy elderly participants (Part 3).

In this trial, we found that single doses of ML-007 oral solution up to and including 164 mg (which is approximately five times the single agent MTD) were well tolerated with the co-administration of PAC oral solution. An intolerable dose was not reached when ML-007 was co-administered with the PAC. Multiple doses of ML-007 up to and including 111 mg co-administered with PAC were well tolerated in a multiple-dosing regimen of five days to seven days in healthy adult and elderly participants, respectively.

Most TEAEs were mild and self-limited in nature and there were no serious adverse events, or SAEs. At fixed single doses of ML-007, TEAE rates declined when the PAC dose was reduced, and a more optimal ratio of pro- and anticholinergic components was achieved. The type, severity, and duration of TEAEs experienced by the healthy elderly participants were similar to those experienced by non-elderly adults.

Study 012

Study ML-007-012, or Study 012, was the first trial to assess the ER ML-007 formulation. It was a two-part, single-center, non-randomized, open-label Phase 1 trial of ML-007 ER administered with or without PAC ER in 24 healthy adult participants. The two-part trial was designed to evaluate the safety, tolerability and PK of single escalating doses of ML-007 ER (with and without PAC ER) and to compare ML-007 solution with ML-007 ER under fed or fasted conditions (Part 1); to evaluate the safety, tolerability and PK of escalating doses of ML-007 ER administered BID with PAC ER (Part 2); and to assess the intended relevant clinical dosing strategy for future trials.

The two-part trial design included:

- Part 1, comprised of two cohorts with eight non-elderly adult participants per cohort (total n=16), with escalation of QD doses up to 250 mg ML-007 ER with PAC ER.
- Part 2, comprised of one cohort with eight non-elderly adult participants (n=8), with escalation of BID doses up to 165 mg ML-007 ER with PAC ER.

The results of Study 012 demonstrated that ML-007 ER administered with or without PAC ER was generally well tolerated. AEs were infrequent, and AE rates were lower than those observed with ML-007 oral solution. All TEAEs observed were mild in severity. There were no moderate or severe AEs with the ER formulation, and no SAEs or deaths. BID dosing did not result in higher rates of TEAEs than once-daily dosing and there were no new TEAEs observed, when compared with previous TEAE profiles associated with ML-007 oral solution administration.

This trial also assessed the safety, tolerability and PK of a novel, orally dissolving tablet, or ODT, formulation of ML-007. The observed data with the ODT formulation was similar to that with oral solution, consistent with its similar PK.

Our Ongoing Clinical Development

Phase 2 ZEPHYR Study for Schizophrenia

We are currently conducting a double-blind, placebo-controlled Phase 2 clinical trial of ML-007C-MA in hospitalized adult patients with a schizophrenia diagnosis who are experiencing an acute exacerbation of psychotic

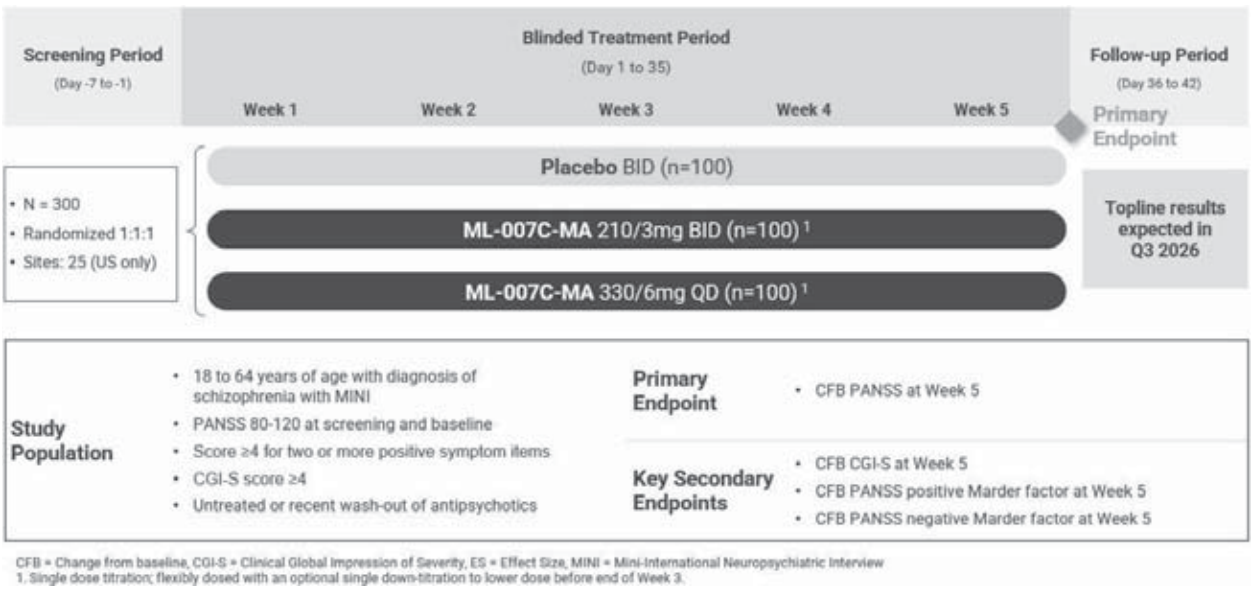
symptoms. We expect to enroll approximately 300 participants in this trial across multiple sites throughout the United States. Patients are randomized 1:1:1 to receive either placebo, ML-007C-MA 210/3mg BID, or ML-007C-MA 330/6mg QD.

Ongoing antipsychotics, if applicable, are discontinued during the screening period. After the wash-out period, participants receive a single titration dose of ML-007C-MA 105/3mg (or placebo) before receiving the maintenance dose (or placebo). Participants are permitted a one-time dose reduction from their target dose, if needed, to address tolerability issues. Participants requiring a dose reduction will remain on the reduced dose for the remainder of the study.

The primary efficacy endpoint is change in total PANSS score from baseline to week 5. Additional key secondary endpoints include changes in the clinical global impression scores and PANSS Marder factor scores. Our multi-pronged approach to study design and conduct to mitigate potential placebo response in the study includes strategic site selection, rigorous patient eligibility review, in-house data monitoring and quality oversight directed by our team.

We expect the trial to reach the target enrollment of 300 participants in April 2026 and report topline results in the third quarter of 2026.

Figure 11: Phase 2 ZEPHYR Trial Design



CFB = Change from baseline, CGI-S = Clinical Global Impression of Severity, ES = Effect Size, MINI = Mini-International Neuropsychiatric Interview
1. Single dose titration; flexibly dosed with an optional single down-titration to lower dose before end of Week 3.

Phase 2 VISTA Trial for ADP

We are conducting a double-blind, placebo-controlled Phase 2 clinical trial of ML-007C-MA for the treatment of hallucinations and delusions associated with ADP. We expect to enroll approximately 300 participants in this trial globally. Participants are randomized 1:1 to receive either placebo or ML-007C-MA 210/3 mg BID.

Eligible participants begin dosing with titration dose of ML-007C-MA 105/1.5mg (or placebo) for one week before receiving the maintenance dose (or placebo). Participants are permitted a one-time dose reduction to the reduced dose, if needed, to address tolerability issues. Participants requiring a dose reduction will remain on the reduced dose for the remainder of the study.

The primary efficacy endpoint is change in NPI-C H+D score from baseline to week 7. Additional secondary endpoints include changes in the clinical global impression scores and NPI-C agitation and aggression scores.

We expect to report topline results from this study in the second half of 2027. In December 2025, ML-007C-MA was granted Fast Track designation by the FDA for the treatment of hallucinations and delusions associated with ADP.

Figure 12: Phase 2 VISTA Trial Design

CFB = Change from baseline, CGI-S = Clinical Global Impression of Severity, NPI-C A+A = Neuropsychiatric Inventory Clinician, Agitation and Aggression, NPI-C H+D = Neuropsychiatric Inventory Clinician, Hallucinations and Delusions.
1. Increase to the target dose of 210/3 mg BID at Week 1, unless the participant is experiencing tolerability issues that, in the investigator's opinion, would preclude a higher dose. Every effort should be made to increase to the target dose as soon as possible up until Week 3. One-time dose reduction to 105/1.5 mg allowed for tolerability.

ML-004 for the Treatment of Autism Spectrum Disorder

Our second product candidate, ML-004, is a 5-$HT_{1B/1D}$ agonist that we are developing for the treatment of social communication deficit and/or irritability in ASD. Historical clinical development efforts for ASD have been challenging given the biological heterogeneity of symptoms across age, developmental level and sex, and the lack of validated outcome measures. There are currently no FDA-approved therapies for the core symptoms of ASD, social communication deficit and repetitive/restricted behavior. The only two therapies approved for ASD-associated irritability are atypical antipsychotics, which are associated with serious side effects. ML-004 is an IR/ER formulation of zolmitriptan. We are currently conducting IRIS, a Phase 2 trial to evaluate the efficacy of ML-004 for the improvement of social communication deficits in patients with ASD. Change from baseline in irritability symptoms is a secondary endpoint. We have completed enrollment in this trial and expect to report topline results in the third quarter of 2026. Based on the results from the IRIS trial, we intend to explore potential strategies for further development of ML-004.

Overview of Autism Spectrum Disorder

ASD is a neurodevelopmental condition characterized by the core features of impaired social communication and restricted / repetitive thoughts and behaviors. In addition to the core symptoms of the disorder, many individuals with ASD experience high rates of comorbid neurobehavioral symptoms, including irritability and aggression (in approximately 25% of ASD patients), hyperactivity and mood lability. Greater impairments in social communication are associated with higher rates of these maladaptive behaviors and decreased social functioning. The prevalence of ASD has been steadily increasing, and approximately 1.8 million U.S. children and adolescents ages 3-17 and over five million adults in the United States are living with ASD. ASD is associated with higher health care and school costs, increased caregiver burden and loss of caregiver income and substantial functional, occupational and quality-of-life impacts to patients and families affected by the condition.

There are no FDA-approved pharmaceutical treatments for the core symptoms of ASD. The only widely accepted intervention with supportive clinical evidence is long-term behavioral therapy, for up to 30-40 hours per week, which can place substantial burdens on families and reduce the amount of school time available to children. The atypical antipsychotics, risperidone and aripiprazole, are approved by the FDA to treat irritability symptoms

associated with ASD. However, both have potentially serious side effects, including increased appetite, weight gain, fatigue, EPS, metabolic changes (hyperglycemia, diabetes mellitus and dyslipidemia), hyperprolactinemia, somnolence and sedation. Additionally, both drugs are ineffective in treating the core social features of the disorder and symptoms often return when the drug is discontinued. The need to find effective treatments to address ASD's core and associated symptoms, therefore, remains significant.

Our Product Candidate, ML-004

ML-004 is an IR/ER oral tablet formulation of the 5-$HT_{1B/1D}$ agonist, zolmitriptan, intended for once-daily dosing for the chronic treatment of social communication deficits and behaviors associated with ASD. Zolmitriptan has been commercially available since 1997 for the acute treatment of migraine headaches in adults. More than 25 million prescriptions have been filled for zolmitriptan in the United States since its launch.

Rationale for 5-HT_{1B} Receptor Agonism for the Treatment of Sociability and Irritability in ASD

Our rationale for this program is built upon the historical association between dysregulated serotonin and ASD pathology. More recent evidence establishing the role of 5-HT_{1B} receptor activation in sociability was generated through experiments in which blocking 5-HT_{1B} receptors disrupted social reward. These findings were further supported by our preclinical work demonstrating that 5-HT_{1B} agonists increased sociability in ASD models and decreased aggression.

Optogenetic experiments have demonstrated that activating the serotonin circuit from the dorsal raphe nucleus, or DRN, to the nucleus accumbens, or NAc, could increase sociability. Conversely, suppressing this serotonin circuit using an inhibitory opsin decreased sociability. In mouse models of ASD, including the 16p11 syntenic deletion model, that show baseline decreases in social behavior, activation of the DRN to NAc circuit significantly increased social interaction, an effect that was blocked by a 5-HT_{1B} antagonist.

An additional set of findings independently established that 5-HT_{1B} activation can increase sociability. This finding emerged from work aimed at identifying circuit biology responsible for the known pro-social effects of methylamphetamine, or MDMA. MDMA is an illicit drug known to cause profound feelings of social connectedness and empathy in humans. In animal models, it was shown that mice treated with MDMA demonstrated dose-dependent increases in social behavior. This increase in sociability was blocked by infusing a 5-HT_{1B} blocker into the NAc, indicating that 5-HT_{1B} receptors located in the NAc are necessary for the pro-social benefits of MDMA.

Our Preclinical Studies

Based on these findings, we hypothesized that a selective 5-HT_{1B} agonist could increase sociability, replicating the pro-social effects of MDMA without the addictive liability. We chose the approved brain-penetrant 5-$HT_{1B/1D}$ agonist zolmitriptan and demonstrated that it could reproduce the pro-social effects of both MDMA and the optogenetic activation of the DRN to NAc circuit in animal models. Zolmitriptan (marketed as ZOMIG) is commonly used in low doses as an acute treatment for migraine headaches, and as such, its IR safety profile has been well established. However, for chronic treatment of social communication deficits and irritability, a different formulation is required. ML-004 is an IR/ER oral tablet designed for chronic use at higher doses than those previously approved, prompting additional studies to establish safety, tolerability and PK prior to Phase 2 efficacy trials.

To evaluate zolmitriptan's potential therapeutic impact in treating sociability and irritability in ASD, we have conducted several in vivo animal studies, including mouse models for valproic acid, or VPA, and CNTNAP2 knock out. These studies demonstrated consistent, statistically significant improvements in sociability and aggression. In both animals and humans, prenatal VPA is known to increase the risk for ASD in offspring. Mice born to mothers treated prenatally with VPA show a higher rate of social deficit. Administration of zolmitriptan at a dose of 10 mg/kg significantly reversed the social deficit in these mice. Neurobiological, genetic and imaging data provide evidence for the CNTNAP2 gene as a risk factor for ASD and related neurodevelopmental disorders. As with the VPA-treated mouse model, treatment with zolmitriptan 10 mg/kg significantly improved the social deficit phenotype in CNTNAP2 KO mice. Our preclinical studies utilized commercially available zolmitriptan.

Our Clinical Trials of ML-004

We have formulated ML-004 for chronic use at higher doses than approved doses for zolmitriptan and have conducted two Phase 1 trials for our ML-004 program to evaluate safety, tolerability and PK. Based on the results of the Phase 1 trials, we are currently conducting a Phase 2 trial in ASD patients to evaluate the safety and efficacy of ML-004 compared with placebo in the improvement of social communication deficits and expect to report results in the third quarter of 2026.

Phase 1 Trial MAP-ZOL-HV-001

We completed a randomized, double-blind, placebo-controlled MAD PK Phase 1 trial that evaluated high-dose IR zolmitriptan oral formulation in a total of 40 healthy adult volunteer participants randomized into five ascending dose study drug cohorts of 5 mg, 10 mg, 20 mg, 30 mg and 40 mg, or placebo dosed three times a day, or TID. The dosing regimen included a two-day to four-day 'up-titration period' followed by a seven-day 'treatment period' at the targeted treatment dose, followed by a two-day to five-day 'down-titration' period.

In this Phase 1 trial, the most common AEs in participants on zolmitriptan were headache, dizziness, nausea and hiccups. These AEs occurred at a higher frequency at the 40 mg TID dose. Most AEs were mild in nature and there were no SAEs. In addition, there were no clinically significant or dose-responsive changes in mean QTc.

Phase 1 Trial ML-004-ER-001

We completed an open-label bioavailability and PK Phase 1 trial that evaluated ML-004 as a zolmitriptan bi-layer IR/ER gastroretentive 24 mg oral tablet formulation (6 mg IR/18 mg ER) in a total of 12 healthy adult participants under fasted and fed conditions. The dosing regimen included 20 mg of zolmitriptan IR on Day 1, 24 mg of ML-004 under fasted conditions on Day 2 and 24 mg of ML-004 under fed conditions on Day 4.

In the trial, a single dose of ML-004 24 mg in healthy adult participants resulted in a prolonged absorption phase and reduced C_{max} compared to IR zolmitriptan. Based on these results, modeled data suggested that ML-004 48 mg and 72 mg would result in target plasma exposure based on preclinical efficacy models for approximately 12-15 hours, respectively.

In the trial, zolmitriptan IR and ML-004 24 mg were generally well tolerated, and AEs were less common with ML-004 dosing than with IR zolmitriptan dosing. All TEAEs were non-serious and mild to moderate. All participants completed the trial, and no participants discontinued or interrupted trial treatment due to AEs.

Ongoing Phase 2 Trial

Our Phase 2 IRIS trial is an ongoing multicenter, randomized, double-blind, placebo-controlled trial that enrolled approximately 160 adolescent (age 12-17) and adult (age 18-45) participants with ASD to evaluate the efficacy of ML-004 compared with placebo in the improvement of core social communication deficits. The trial employs a flexible dosing paradigm (target maintenance doses of ML-004 include 24 mg, 48 mg and 72 mg), and the primary endpoint (change from baseline to the end of the maintenance dosing on the Autism Behavior Inventory, Social Communication Domain Score) is assessed after 12 weeks of maintenance dosing. A key secondary endpoint includes the change from baseline on the Aberrant Behavior Checklist-Irritability, or ABC-I, for patients whose ABC-I score at baseline represented moderate or greater irritability.

Following completion of the antecedent IRIS trial, patients are eligible to participate in an active 52-week open-label extension trial designed to assess the long-term safety of ML-004 administration.

We have completed enrollment in this trial and expect to report topline results in the third quarter of 2026. Based on the results from the IRIS trial, we intend to explore potential strategies for further development of ML-004.

Preclinical Programs

ML-009

ML-009 is our GPR52 PAM program, which we are developing for the treatment of hyperactivity, impulsivity and agitation-related disorders. GPR52 is an orphan receptor that is selectively expressed in the indirect pathway neurons of the striatum, where it regulates neuronal function through activation of cAMP-dependent pathways. GPR52 is co-localized with dopamine D2 receptors, which are the primary target of antipsychotics. Activation of GPR52 opposes the actions of D2 receptors and increases the activity of indirect pathway striatal neurons.

In preclinical studies, GPR52 activation reduced stimulant-induced hyperactivity, impulsivity and aggression, without causing catalepsy. Using our internal medicinal chemistry, we have identified multiple novel potential product candidates that are selective, orally bioavailable positive modulators of GPR52. We have nominated a preclinical product candidate for further advancement and expect to complete IND-enabling studies in 2027.

ML-055

ML-055 is our next-generation, novel M_1/M_4 muscarinic agonist program, which we are developing for the treatment of neuropsychiatric conditions. Leveraging our experience with ML-007, we have continued to discover and develop multiple novel chemical series of M_1/M_4 agonists with varying potency, pharmacology and chemical properties. Preclinical in vitro and in vivo studies evaluating multiple potential candidates have demonstrated significantly greater potency relative to ML-007 and the potential for once-daily dosing and long-acting injectable formulation. We expect to nominate a preclinical candidate to advance to IND-enabling studies in 2026.

ML-021

ML-021 is our M_4 antagonist program for the treatment of motor deficits in Parkinson's disease. ML-021 is designed to selectively target the muscarinic M_4 receptors, which are highly expressed in direct pathway neurons of the striatum. Loss of striatal dopamine in Parkinson's disease results in an increase in striatal acetylcholine, which activates M_4 receptors on direct pathway neurons and is predicted to reduce their activity and contribute to motor deficits in Parkinson's disease. Anticholinergic agents have been used for decades to treat Parkinson's disease, but their utility is limited by antagonist activity at M_1 receptors that is linked to adverse effects including cognitive impairment, psychosis, and constipation. Selective antagonism of the M_4 receptor is predicted to increase the activity of the direct pathway and improve motor symptoms in Parkinson's disease without the unwanted side effects associated with M_1 antagonism. This mechanism is supported by optogenetic experiments in which activation of the direct pathway enhanced movement and rescued motor deficits in Parkinson's disease.

We have shown significant improvements in motor deficits in animal models of Parkinson's disease using multiple potential candidates and tool compounds. We have conducted preclinical studies using multiple potential candidates, including our lead preclinical candidate, and expect to finalize a preclinical candidate to advance to IND-enabling studies in 2027.

Intellectual Property

Overview of our Intellectual Property

Our success depends in part on our ability to obtain and maintain protection of intellectual property, particularly patents, in the United States and other countries with respect to product candidates and technology that are important to our business. We are actively building our intellectual property portfolio around our product candidates and discovery programs and have developed numerous patents and patent applications and possess substantial know-how and trade secrets relating to the development and commercialization of our neuropsychiatric product candidates. In addition to patent protection, we also rely on trade secrets to protect aspects of our business for which we do not consider patent protection appropriate. For information regarding risks related to our intellectual property, see the section titled "Risk Factors—Risks Related to Our Intellectual Property."

As of December 31, 2025, our patent estate contains approximately 86 issued patents and pending patent applications directed to our product candidates and certain of our proprietary technology, inventions, and improvements. In the United States, we own four issued patents, four pending non-provisional patent applications, and three pending provisional patent applications. We also own two pending Patent Cooperation Treaty, or PCT, applications. In jurisdictions outside of the United States, we own approximately 73 issued patents and pending patent applications that, in some cases, are counterparts to the foregoing U.S. patents and patent applications.

Our patent estate, which includes protection for our clinical and preclinical product candidates, as of December 31, 2025, is summarized below.

ML-007C-MA

As of December 31, 2025, we own three issued U.S. patents covering the composition of matter of ML-007 and one issued U.S. patent covering the use of ML-007 to treat, among other things, schizophrenia and ADP. The issued patents covering the composition of matter of ML-007 are expected to expire between 2031 and 2032, exclusive of possible patent term adjustments or extensions or other forms of exclusivity, and the issued patent covering the use of ML-007 to treat schizophrenia and ADP is expected to expire in 2031, exclusive of possible patent term adjustments or extensions or other forms of exclusivity. We also own one pending U.S. application and 16 pending foreign applications (in Australia, Bahrain, Canada, China, the EPO, Eurasia, Hong Kong, Israel, Japan, the Republic of Korea, Kuwait, Mexico, New Zealand, Oman, Singapore and the United Arab Emirates) and two U.S. provisional applications directed to the combination of ML-007 and a PAC to treat, among other things, schizophrenia and ADP. Any patents issuing from these applications, if granted, will be expected to expire in 2042, exclusive of possible patent term adjustments or extensions or other forms of exclusivity and any patents issuing from patent applications that claim priority to these provisional applications, if granted, will be expected to expire in 2046, exclusive of possible patent term adjustments or extensions or other forms of exclusivity. We also own one U.S. application and 18 pending foreign applications (in Australia, Bahrain, Brazil, Canada, China, Europe, Israel, India, Japan, Korea, Kuwait, Mexico, New Zealand, Oman, Russia, Saudi Arabia, Singapore, and the United Arab Emirates) directed to pharmaceutical compositions containing ML-007 and a PAC, and the use of such pharmaceutical compositions, to treat, among other things, schizophrenia and ADP. Any patents issuing from these applications, if granted, will be expected to expire in 2044, exclusive of possible patent term adjustments or extensions or other forms of exclusivity. Additionally, we own one pending PCT application covering salts and crystalline polymorphs of ML-007. Any patents issuing from this PCT application, if granted, will be expected to expire in 2045, exclusive of possible patent term adjustments or extensions or other forms of exclusivity.

ML-004

As of December 31, 2025, we own five issued foreign patents (in the EPO, Japan, Singapore, the Russian Federation, and Mexico), one pending U.S. application and 13 pending foreign applications (in Australia, Canada, China, the EPO, Hong Kong, Israel, Japan, the Republic of Korea, Mexico, New Zealand, the Russian Federation, Singapore and South Africa) directed to the use of ML-004 to treat, among other things, the symptoms of ASD. Any patents issuing from these pending patent applications, if granted, will be expected to expire in 2040, exclusive of possible patent term adjustments or extensions or other forms of exclusivity. We also own one pending U.S. application and 21 pending foreign applications (in Australia, Bahrain, Brazil, Canada, China, the EPO, Hong Kong, Israel, India, Japan, the Republic of Korea, Kuwait, Mexico, New Zealand, Oman, Qatar, the Russian Federation, Saudi Arabia, Singapore, South Africa and the United Arab Emirates) directed to our IR/ER oral ML-004 compositions and their use to treat the symptoms of ASD. Any patents issuing from these pending patent applications, if granted, will be expected to expire in 2042, exclusive of possible patent term adjustments or extensions or other forms of exclusivity.

ML-009

As of December 31, 2025, we own one pending PCT application directed to small molecule GPR52 agonists. Any patents issuing from this PCT application will be expected to expire in 2044, exclusive of possible patent term adjustments or extensions or other forms of exclusivity.

ML-055

As of December 31, 2025, we own one pending U.S. provisional application directed to small molecule M_1/M_4 muscarinic agonists. Any patents issuing from patent applications that claim priority to this provisional application, if granted, will be expected to expire in 2046, exclusive of possible patent term adjustments or extensions or other forms of exclusivity.

ML-021

As of December 31, 2025, we own one pending U.S. provisional application directed to small molecule M_4 antagonists. Any patents issuing from patent applications that claim priority to this provisional application, if granted, will be expected to expire in 2046, exclusive of possible patent term adjustments or extensions or other forms of exclusivity.

Patents

Individual patents have terms for varying periods depending on the date of filing of the patent application or the date of patent issuance and the legal term of patents in the countries in which they are obtained. Generally, utility patents issued for applications filed in the United States are granted a term of 20 years from the earliest effective filing date of a non-provisional patent application. The duration of foreign patents varies in accordance with provisions of applicable local law, but typically is also 20 years from the earliest effective filing date. With regard to our U.S. provisional patent applications, if we do not file any corresponding non-provisional patent applications within 12 months of the provisional patent application filing date, we may lose our priority date with respect to our provisional patent applications and any patent protection on the inventions disclosed in our provisional patent applications. All taxes, annuities or maintenance fees for a patent, as required by the U.S. Patent and Trademark Office and certain foreign jurisdictions, must be timely paid in order for the patent to remain in force during this period of time.

The actual protection afforded by a patent may vary on a product-by-product basis, from country to country and can depend upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions and the availability of legal remedies in a particular country and the validity and enforceability of the patent. Our patents and patent applications may be subject to procedural or legal challenges by others. We may be unable to obtain, maintain and protect the intellectual property rights necessary to conduct our business, and we may be subject to claims that we infringe or otherwise violate the intellectual property rights of others, which could materially harm our business. For more information, see the section titled "Risk Factors—Risks Related to Our Intellectual Property."

Trademarks, Trade Secrets and Proprietary Information

In addition to patents, we rely on trademarks, trade secrets, and know-how relating to our proprietary technology and programs, continuing innovation, and in-licensing opportunities to develop, strengthen and maintain our proprietary position in the field of neuropsychiatric medicine. As of February 25, 2026, our trademark portfolio currently contains seven trademark registrations in the United States, European Union, United Kingdom, China, Japan and South Korea for the mark "MAPLIGHT THERAPEUTICS."

We rely upon unpatented trade secrets and know-how and continuing technological innovation to develop and maintain our competitive position. However, trade secrets and know-how can be difficult to protect. We seek to protect our proprietary information, in part, by executing confidentiality agreements with our collaborators and scientific advisors and non-competition, non-solicitation, confidentiality and invention assignment agreements with our employees, consultants and independent contractors. We have also executed agreements requiring assignment of inventions with selected scientific advisors and collaborators. The confidentiality agreements we enter into are designed to protect our proprietary information, and the agreements or clauses requiring assignment of inventions to us are designed to grant us ownership of technologies that are developed through our relationship with the respective counterparty. We cannot guarantee, however, that we have executed such agreements with all applicable counterparties, such agreements will not be breached, or that these agreements will afford us adequate protection of

our intellectual property and proprietary rights. See the section titled "Risk Factors—Risks Related to our Intellectual Property."

NeuroSolis Asset Purchase Agreement

On June 18, 2020, we entered into an Asset Purchase Agreement with NeuroSolis, Inc., or NeuroSolis, to acquire its proprietary M_1/M_4 agonist molecules and associated intellectual property.

Pursuant to that agreement, NeuroSolis sold us its assets related to both its proprietary M_1/M_4 agonist molecules, and its program for the identification of molecules that modulate the activity of the muscarinic M_1 receptor or the muscarinic M_4 receptor. We did not assume any liabilities of NeuroSolis in connection with our purchase of these assets. We are obligated to use commercially reasonable efforts to achieve specified development and regulatory milestones by certain achievement dates by developing a product covered by a transferred patent, including ML-007C-MA. In May 2024, we and NeuroSolis entered into a Waiver of Milestone Deadline pursuant to which NeuroSolis agreed to waive the milestone achievement date for one of the specified development milestones, which we subsequently achieved in June 2025.

We have made upfront and development milestone payments of $150,000 in the aggregate to NeuroSolis. In addition, we agreed to issue NeuroSolis up to an aggregate of 62,083 shares of our common stock, contingent upon the occurrence of specified development and regulatory milestones, of which we issued 26,607 shares in June 2025 upon the achievement of a specified milestone.

Manufacturing

We do not own or operate and currently have no plans to purchase or establish any manufacturing facilities. We have engaged and expect to continue to rely on well-established third-party contract manufacturing organizations, or CMOs, to supply our product candidates for use in our preclinical studies and clinical trials. We intend to continue to rely on CMOs for later-stage development and commercialization of our product candidates, including any additional product candidates that we may identify. Because we rely on contract manufacturers, we employ personnel with extensive technical, manufacturing, analytical and quality experience to oversee 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.

Sales and Marketing

We do not currently have a commercial organization for the marketing, sales and distribution of 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 sales, marketing 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 the United States. As our current and future product candidates progress through clinical development, 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 and manufacturing needs may all influence our commercialization strategies.

Competition

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on intellectual property. While we believe our product candidates, approach, knowledge, experience and scientific resources provide us with competitive advantages, we face potential competition from many different sources, including pharmaceutical and biotechnology companies, academic institutions and governmental agencies, as well as public and private research institutions. Any product candidates that we successfully develop and commercialize will compete with approved treatment options, off-label therapies and new therapies that may become available in the future.

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

Our commercial opportunity could be reduced or eliminated if competitors develop and commercialize products that are safer and more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Competitors also may obtain FDA or other regulatory approval for their products more rapidly or earlier than us, which could result in our competitors establishing a strong market position before we are able to enter the market. Additionally, technologies developed by our competitors may render our potential product candidates uneconomical or obsolete, and we may not be successful in marketing our product candidates against competitors.

Schizophrenia

We are developing ML-007C-MA for the treatment of schizophrenia. While there remains significant unmet need in schizophrenia, we may face competition from typical and atypical antipsychotic treatments that work primarily by inhibiting dopamine receptors.

We are aware of several product and product candidates in clinical development that modulate muscarinic receptors, such as Cobenfy (also known as KarXT), which is currently marketed by Bristol Myers Squibb Company for the treatment of schizophrenia; emraclidine, which is being developed by AbbVie Inc.; and direclidine, NBI-'570 and NBI-'567, which are being developed by Neurocrine Biosciences, Inc. In addition, we are aware of other companies that are in earlier stages of developing muscarinic agents for schizophrenia, as well as other CNS indications, including Neumora Therapeutics, Inc. and Syremis Therapeutics Ltd.

We may also face competition from other companies developing product candidates that modulate other receptors for the treatment of schizophrenia.

Alzheimer's Disease Psychosis

We are also developing ML-007C-MA for the treatment of ADP. Despite the severity of the condition, there are no FDA-approved medicines indicated for the treatment of patients with ADP. In the absence of approved treatments and reflecting significant unmet medical need, atypical and even some typical antipsychotics are used as off-label treatments. We are aware of several product candidates in clinical development that are designed to modulate muscarinic receptors, including Cobenfy, which is being developed by Bristol Myers Squibb Company.

We may also face competition from other companies developing product candidates to address ADP that modulate other receptors, including ACP-204, which is being developed by Acadia Pharmaceuticals, Inc. We may also face competition from other companies developing product candidates to address agitation or other behavioral symptoms associated with Alzheimer's disease.

Autism Spectrum Disorder

We are developing ML-004 for the treatment of ASD. Given the lack of approved, effective and safe treatment options, there is a significant unmet need for an effective therapeutic option for the treatment of social communication deficits in ASD. In the treatment of the irritability symptoms associated with ASD, we may face competition from ABILIFY, marketed by Otsuka Pharmaceutical Co., Ltd., and RISPERDAL, marketed by Johnson & Johnson, as well as from generic forms of those drugs that are being marketed and sold.

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 products such as those we are developing. A new drug must be approved by the FDA through the New Drug Application, or NDA, process before it may be legally marketed in the United States.

U.S. Drug Development Process

In the United States, the FDA regulates drugs under the federal Food, Drug and Cosmetic Act, or FDCA, and its implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state and local statutes and regulations require the expenditure of substantial time and financial resources. 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 Good Laboratory Practice regulations and other applicable regulations;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- approval by an IRB or ethics committee at each clinical site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with Good Clinical Practice, or GCP, regulations to evaluate the safety and efficacy of the product candidate for its intended use;
- submission to the FDA of an NDA after completion of all pivotal trials;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with current Good Manufacturing Practice, or cGMP, regulations to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;
- satisfactory completion of potential inspection of selected clinical investigation sites to assess compliance with GCP regulations; and
- FDA review and approval of the NDA to permit commercial marketing of the product for particular indications for use in the United States.

Once a product candidate is identified for development, it enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information and analytical data, to the FDA as part of an IND. An IND is a request for allowance from the FDA to administer an investigational drug product to humans. An IND will also include a 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 includes an efficacy evaluation. Some preclinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, places the clinical trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Clinical holds also may be imposed by the FDA at any time before or during clinical trials due to safety concerns about ongoing or proposed clinical trials or non-compliance with specific FDA requirements, and in such case, the trials may not begin or continue until the FDA notifies the sponsor that the hold has been lifted.

All clinical trials must be conducted under the supervision of one or more qualified investigators in accordance with GCP regulations, which include the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial. Clinical trials must be conducted under protocols detailing the objectives of the trial, dosing procedures, subject selection and exclusion criteria and the safety and

effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND, and a separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. 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 and written IND safety reports must be submitted to the FDA and investigators for serious and unexpected suspected AEs, 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 at each institution participating in the clinical trial must review and approve each protocol before a clinical trial commences at that institution and must also approve the information regarding the trial and the consent form that must be provided to each trial subject or his or her legal representative, monitor the trial until completed and otherwise comply with IRB regulations. The FDA or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. In addition, some clinical trials are overseen by an independent group of qualified experts organized by the sponsor, known as a data safety monitoring board or committee. Depending on its charter, this group may determine whether a trial may move forward at designated check points based on access to certain data from the trial. There are also requirements governing the reporting of ongoing clinical trials 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 with the target disease or condition, and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion 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 appropriate 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.

Post-approval trials, sometimes referred to as Phase 4 trials, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA.

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

FDA Regulatory Framework for Fixed-Combination Prescription Drugs for Humans

The FDA's regulation at 21 CFR § 300.50 governing fixed-combination drug products provides, among other things, that two or more drugs may be combined in a single dosage form when each component contributes to the claimed effects and the dosage of each component (amount, frequency, duration) is such that the combination is safe and effective for a significant patient population requiring such concurrent therapy as defined in the labeling for the

drug. This rule is meant to ensure that any fixed-dose combination drug provides an advantage to the patient over and above that obtained when one of the individual ingredients is used in the usual safe and effective dose.

U.S. Review and Approval Process

The results of product development, preclinical and other non-clinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the drug, proposed labeling and other relevant information are submitted to the FDA as part of an NDA requesting approval to market the product. The submission of an NDA is subject to the payment of substantial user fees; a waiver of such fees may be obtained under certain limited circumstances.

Once an NDA has been submitted, the FDA conducts a preliminary review of the application within the first 60 days after submission, before accepting it for filing, to determine whether it is 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 its manufacturing is cGMP-compliant to assure and preserve the product's identity, strength, quality and purity. Under the Prescription Drug User Fee Act, or PDUFA, guidelines that are currently in effect, the FDA has a goal of ten months from the date of "filing" of a standard NDA for a new molecular entity to review and act on the submission. This review typically takes twelve months from the date the NDA is submitted to FDA because the FDA has approximately two months to make a "filing" decision after the application is submitted.

The FDA may refer an application for a novel drug to an advisory committee. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. Before approving an NDA, the FDA will typically inspect the facility or facilities where the product is manufactured. Additionally, before approving an NDA, the FDA may inspect one or more clinical trial sites to assure compliance with GCP regulations.

After the FDA evaluates an NDA and conducts inspections of manufacturing facilities where the investigational product and/or its drug substance will be produced, the FDA may issue an approval letter or a Complete Response Letter, or CRL. An approval letter authorizes commercial marketing of the drug with prescribing information for specific indications. 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 and may require additional clinical data, such as additional clinical trials or other significant and time-consuming requirements related to clinical trials, nonclinical studies or manufacturing. If a CRL is issued, the sponsor must resubmit the NDA addressing all of the deficiencies identified in the letter or withdraw the application. Even if such data and information are submitted, the FDA may decide that the NDA does not satisfy the criteria for approval.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. In addition, the FDA may require a sponsor to conduct "Phase 4" testing, which involves clinical trials designed to further assess a drug's safety and/or effectiveness following NDA approval, and may require additional testing and surveillance programs to monitor the safety of approved products that have been commercialized. The FDA may also place other conditions on approval including the requirement for a risk evaluation and mitigation strategy, or REMS, to assure the safe use of the drug. If the FDA concludes a REMS is needed, the sponsor of the NDA must submit a proposed REMS. The FDA will not approve the NDA without an approved REMS, if required. A REMS could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products.

In addition, the Pediatric Research Equity Act, or PREA, requires a sponsor to conduct pediatric clinical trials for most drugs, for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration. Under PREA, original NDAs and certain supplements must contain a pediatric assessment unless the

sponsor has received a deferral or waiver. The required assessment must evaluate the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and support dosing and administration for each pediatric subpopulation for which the product is deemed safe and effective. The sponsor or FDA may request a deferral of pediatric clinical trials for some or all of the pediatric subpopulations. A deferral may be granted for several reasons, including a finding that the drug is ready for approval for use in adults before pediatric clinical trials are complete or that additional safety or effectiveness data needs to be collected before the pediatric clinical trials begin. The FDA must send a non-compliance letter to any sponsor that fails to submit the required assessment, keep a deferral current or fails to submit a request for approval of a pediatric formulation.

Expedited Development and Review Programs

The FDA has 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 meet certain criteria. Specifically, investigational drugs are eligible for Fast Track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. The sponsor of a Fast Track product candidate has opportunities for more frequent interactions with the applicable FDA review team during product development and, once an NDA is submitted, the application may be eligible for priority review. With regard to a Fast Track product candidate, 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 or biologics, 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.

Any product candidate submitted to the FDA for approval, including a product candidate with a Fast Track designation or breakthrough designation, may also be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. An NDA is 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. The FDA will attempt to direct additional resources to the evaluation of an NDA designated for priority review in an effort to facilitate the review. The FDA endeavors to review applications with priority review designations within six months of the filing date as compared to ten months for review of new molecular entity NDAs under its current PDUFA review goals.

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

Fast Track designation, breakthrough therapy designation, priority review, and accelerated approval do not change the standards for approval but 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

Any products manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, 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. Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP regulations and other laws and regulations. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP regulations and other aspects of regulatory compliance.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including AEs of unanticipated severity or frequency, or with manufacturing processes or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of requirements for post-market trials or clinical trials to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include:

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

In addition, the FDA closely regulates the marketing, labeling, advertising and promotion of drug products. A company can make only those claims relating to safety and efficacy that are approved by the FDA and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe 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. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products.

Hatch-Waxman Act

Section 505 of the FDCA describes three types of marketing applications that may be submitted to the FDA to request marketing authorization for a new drug. A Section 505(b)(1) NDA is an application that contains full reports of investigations of safety and efficacy. A 505(b)(2) NDA is an application that contains full reports of investigations of safety and efficacy but where at least some of the information required for approval comes from investigations that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. This regulatory pathway enables the applicant to rely, in part, on the FDA's prior findings of safety and efficacy for an existing product, or published literature, in support of its application. Section 505(j) establishes an abbreviated approval process for a generic version of approved drug products through the submission of an Abbreviated New Drug Application, or ANDA. An ANDA provides for marketing of a generic drug product that has the same active ingredients, dosage form, strength, route of administration, labeling, performance characteristics and intended use, among other things, to a previously approved product. ANDAs are termed "abbreviated" because they are generally not required to include preclinical (animal) and clinical (human) data to establish safety and efficacy. Instead, generic applicants must scientifically demonstrate that their product is bioequivalent to, or performs in the same manner as, the innovator drug through in vitro, in vivo, or other testing. The generic version must deliver the same amount of active ingredients into a subject's bloodstream in the same amount of time as the innovator drug and can often be substituted by pharmacists under prescriptions written for the reference listed drug. In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent with claims that cover the applicant's drug or a method of using the drug. 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, or the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential competitors in support of approval of an ANDA or 505(b)(2) NDA.

Upon submission of an ANDA or a 505(b)(2) NDA, an applicant must certify to the FDA that (1) no patent information on the drug product that is the subject of the application has been submitted to the FDA; (2) such patent has expired; (3) the date on which such patent expires; or (4) such patent is invalid or will not be infringed upon by the manufacture, use or sale of the drug product for which the application is submitted. Generally, the ANDA or 505(b)(2) NDA cannot be approved until all listed patents have expired, except where the ANDA or 505(b)(2) NDA applicant challenges a listed patent through the last type of certification, also known as a paragraph IV certification. If the applicant does not challenge the listed patents or indicates that it is not seeking approval of a patented method of use, the ANDA or 505(b)(2) NDA application will not be approved until all of the listed patents claiming the referenced product have expired. If the ANDA or 505(b)(2) NDA applicant has provided a Paragraph IV certification to the FDA, the applicant must send notice of the Paragraph IV certification to the NDA and patent holders once the application has been accepted for filing 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. If the Paragraph IV certification is challenged by an NDA holder or the patent owner(s) asserts a patent challenge to the Paragraph IV certification, the FDA may not approve that application until the earlier of 30 months from the receipt of the notice of the Paragraph IV certification, the expiration of the patent, when the infringement case concerning each such patent was favorably decided in the applicant's favor or settled or such shorter or longer period as may be ordered by a court. This prohibition is generally referred to as the 30-month stay. In instances where an ANDA or 505(b)(2) NDA applicant files a Paragraph IV certification, the NDA holder or patent owner(s) regularly take action to trigger the 30-month stay, recognizing that the related patent litigation may take many months or years to resolve. Thus, approval of an ANDA or 505(b)(2) NDA could be delayed for a significant period of time depending on the patent certification the applicant makes and the reference drug sponsor's decision to initiate patent litigation.

Marketing Exclusivity

Market exclusivity provisions under the FDCA can delay the submission or the approval of certain marketing applications. The FDCA provides a five-year period of non-patent 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 505(b)(2) NDA submitted by another company for another drug based on the same active moiety, regardless of whether the drug is intended for the same indication as the original innovative drug or for another indication, where the applicant does not own or have a legal right of reference to all the data required for approval.

However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement to one of the patents listed with the FDA by the innovator NDA holder.

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

Pediatric exclusivity is another type of marketing exclusivity available in the United States. Pediatric exclusivity provides for an additional six months of marketing exclusivity attached to another period of existing exclusivity or an available patent term if a sponsor conducts clinical trials in children in response to a "written request" from the FDA. The issuance of a written request does not require the sponsor to undertake the described clinical trials, and the FDA's grant of pediatric exclusivity does not require the FDA to approve labeling containing information on pediatric use based on the studies conducted.

Healthcare Laws and Regulations

We are subject to healthcare regulation and enforcement by the federal government and the states and foreign governments in which that may constrain the business or financial arrangements and relationships through which we research, market, sell and distribute our drugs, if we obtain marketing approval. The healthcare laws and regulations that may affect our ability to operate include the following:

- The federal Anti-Kickback Statute makes it illegal for any person or entity to knowingly and willfully, directly or indirectly, solicit, receive, offer or pay any remuneration that is in exchange for or to induce the referral of business, including the purchase, order, lease of any good, facility, item or service for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. The term "remuneration" has been broadly interpreted to include anything of value.
- Federal false claims and false statement laws, including the federal civil False Claims Act and civil monetary penalties laws, prohibit, among other things, any person or entity from knowingly presenting, or causing to be presented, for payment to, or approval by, federal programs, including Medicare and Medicaid, claims for items or services, including drugs, that are false or fraudulent.
- The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created additional federal criminal statutes that prohibit among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors or making any false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services.
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and their implementing regulations, imposes obligations on covered entities, including certain healthcare providers, health plans, and healthcare clearinghouses and their respective business associates and covered subcontractors that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information.
- The federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to CMS information related to payments or other transfers of value made to physicians (as defined to include doctors of medicine, dentists, optometrists, podiatrists and chiropractors by such law), other healthcare professionals (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.

Also, many states have similar laws and regulations, such as anti-kickback and false claims laws that may be broader in scope and may apply regardless of payor, in addition to items and services reimbursed under Medicaid and other state programs. Additionally, we may be subject to state 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 federal government's and/or pharmaceutical industry's voluntary compliance guidelines, 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, state laws that require drug manufacturers to report information on the pricing of certain drugs, state and local laws that require the registration of pharmaceutical sales representatives, as well as state and foreign laws governing the privacy and security of personal information, including health information, many of which differ from each other in significant ways and often are not preempted by HIPAA.

Ensuring that our business operations and arrangements with third parties comply with applicable healthcare laws and regulations will likely be costly. If our operations were found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, possible exclusion from government funded healthcare programs, such as Medicare and Medicaid, ongoing governmental oversight, contractual damages, reputational harm, diminished profits and future earnings and curtailment of our operations.

Additionally, to the extent that our products are sold in a foreign country, we may be subject to similar foreign laws.

Coverage and Reimbursement

Successful sales of our products in the U.S. market, if approved, will depend, in part, on the extent to which our products will be covered by third-party payors, such as government health programs like Medicaid and Medicare, or private health insurance (including managed care plans). Patients generally rely on such third-party payors to cover all or part of the costs associated with their health care, and therefore obtaining formulary status and adequate coverage from third-party payors is critical to new and ongoing product acceptance. Although antipsychotics are currently a protected class, formulary status and coverage for drug products can differ significantly from payor to payor as there is no uniform policy of coverage and reimbursement for drug products among third-party payors in the United States. There may be significant delays in obtaining formulary status and coverage, as the process of determining coverage is often time consuming and costly. A third-party payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a drug product does not ensure that other payors will also provide coverage for the drug product. Third-party payors are increasingly reducing coverage for medical drugs and services and implementing measures to control utilization of drugs (such as requiring prior authorization for coverage). Patient copays can be significant and may vary among products within a class depending upon the formulary status of an agent with a particular payor. Inconsistencies in formulary status across state Medicaid plans and commercial payors may result in coverage gaps in some geographical areas.

Additionally, the containment of healthcare costs has become a priority of federal and state governments, and the prices of drugs have been a focus in this effort. The U.S. government, state legislatures, and foreign governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on coverage and requirements for substitution of generic drugs. 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 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.

Adoption or expansion of price controls and cost-containment measures could further limit our net revenue and results. Decreases in third-party coverage for our product candidates, if approved, or a decision by a third-party payor to not cover our product candidates could have a material adverse effect on our sales, results of operations, and financial condition.

General legislative cost control measures may also affect reimbursement for our products. If we obtain approval to market a product candidate in the United States, we may be subject to spending reductions affecting Medicare, Medicaid or other publicly funded or subsidized health programs and/or any significant taxes or fees.

U.S. Healthcare Reform

The U.S. government, state legislatures, and foreign governments have shown significant interest in implementing cost containment programs to limit the growth of government-paid healthcare costs, including price-controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs.

For example, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the ACA, was enacted in the United States in 2010 and substantially changed the way healthcare is financed by both the government and private insurers. Since its enactment, there have been executive, judicial and Congressional challenges to certain aspects of the ACA. For example, on July 4, 2025, the One Big Beautiful Bill Act, or 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. We are unable to predict the future course of federal or state healthcare legislation in the U.S. directed at broadening the availability of healthcare and containing or lowering the cost of healthcare, particularly in light of the recent U.S. Presidential and Congressional elections. The current Trump administration is pursuing policies to reduce regulations and expenditures across government, 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 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 and proposals include, for example (1) reducing 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, in *Loper Bright Enterprises v. Raimondo*, the U.S. Supreme Court 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, among other things, impact the drug approval process and make changes to modify the Medicare Drug Price Negotiation Program.

At the state level, legislatures and state agencies have increasingly passed legislation and implemented regulations that are designed to control pharmaceutical and biological product pricing, including price or reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, that are designed to encourage importation from other countries and bulk purchasing. Some states have enacted legislation creating so-called prescription drug affordability boards, which ultimately may attempt to impose price limits on certain drugs in these states, while some states are also seeking to implement general, across-the-board price caps for pharmaceuticals, or are seeking to regulate drug distribution. Legally mandated price controls on payment amounts by third-party payors or other restrictions could materially and adversely impact our business, financial condition, results of operations and prospects. In addition, regional

healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs.

Existing healthcare reform measures, as well as the implementation of additional cost containment measures or other reforms, may prevent us from being able to generate revenue, attain profitability or commercialize our product candidates, if approved.

Data Privacy and Security

Numerous state, federal, and foreign laws, regulations, standards, and other obligations govern the collection, use, dissemination, access to, confidentiality, and security of health-related and other personal data, including clinical trial data. In the United States, numerous federal and state laws and regulations, including data breach notification laws, health information privacy and security laws, including HIPAA, and consumer protection laws and regulations, including Section 5 of the Federal Trade Commission Act, govern the collection, use, disclosure and protection of health-related and other personal data. Outside of the United States, many jurisdictions also have laws governing the privacy and security of personal data, including health-related data, such as the European Union's General Data Protection Regulation, and impose stringent obligations on covered entities. In addition, use of artificial intelligence or machine learning technology is subject to evolving laws and regulations, including obligations to mitigate risks of bias and anti-discrimination. We and certain of the third parties with whom we work face cybersecurity risks that threaten the confidentiality, integrity and availability of our IT systems and personal data, including health-related data.

Privacy and security laws, regulations and other obligations are constantly evolving, may conflict with each other to complicate compliance efforts, and in the event of a security incident or our actual or perceived failure to comply with such laws, regulations and obligations can result in investigations, proceedings or actions that lead to significant civil and/or criminal penalties, private litigation and restrictions on data processing, disgorgement of software algorithms trained on health-related data, or other material adverse consequences.

Additional Regulation

In addition to the foregoing, state and federal laws regarding environmental protection and hazardous substances, including the Occupational Safety and Health Act, the Resource Conservation and Recovery Act and the Toxic Substances Control Act, may affect our business. These and other laws govern the use, handling and disposal of various biologic, chemical and radioactive substances used in, and wastes generated by, 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. Equivalent laws have been adopted in other countries that impose similar obligations.

Foreign Corrupt Practices Act

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

Employees and Human Capital Resources

As of December 31, 2025, we had 133 full-time employees and no part-time employees. Our employees are not represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our employees. We believe our success depends on our ability to attract, retain, develop and motivate diverse, highly skilled personnel. In particular, we depend upon the personal efforts and abilities of the principal members of our senior management to partner effectively as a team and to provide strategic direction, develop our business, manage our operations and maintain a cohesive and stable work environment. We also rely on qualified managers and skilled employees, such as scientists, engineers and laboratory technicians, with technical expertise in operations, scientific knowledge, engineering skills and quality management experience in order to operate our business successfully.

Our compensation program is designed to retain, motivate and, as needed, attract highly qualified employees. Accordingly, we offer a mix of competitive base salary, cash-based annual incentive compensation, performance-based equity compensation awards and other employee benefits.

Corporate Information

We were incorporated under the laws of the State of Delaware in November 2018 as Alvarado Therapeutics, Inc. In August 2019, we changed our name to MapLight Therapeutics, Inc. Our principal executive offices are located at 800 Chesapeake Drive, Redwood City, California 94063 and our telephone number is (617) 984-6300.

Available Information

We maintain an internet website at www.maplightrx.com and make available free of charge through our website 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 Securities Exchange Act of 1934, as amended, or the Exchange Act. We make these reports available through our website as soon as reasonably practicable after we electronically file such reports with, or furnish such reports to, the Securities and Exchange Commission, or the SEC.

The information on our website is not incorporated by reference into this Annual Report and should not be considered to be a part of this Annual Report. Our website address is included in this Annual Report as an inactive technical reference only.

Item 1A. Risk Factors.

The following information sets forth risk factors that could cause our actual results to differ materially from those contained in forward-looking statements we have made in this Annual Report on Form 10-K and those we may make from time to time. You should carefully consider the risks described below, in addition to the other information contained in this Annual Report on Form 10-K and our other public filings. Our business, financial condition or results of operations could be harmed by any of these risks. The risks and uncertainties described below are not the only ones we face. Additional risks not presently known to us or other factors not perceived by us to present significant risks to our business at this time also may impair our business operations.

Risks Related to Our Limited Operating History, Financial Condition and Need for Additional 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 product candidates and the prospects for our future viability.

We are a clinical-stage biopharmaceutical company with a limited operating history. We were formed in 2018 and our operations to date have been limited to organizing, staffing and financing our company, and conducting research and development activities, including developing our platform, conducting clinical trials for our product candidates and establishing our intellectual product portfolio. If we are successful in achieving regulatory approval for our product candidates, 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 product candidates is unproven, and we do not know whether we will be able to develop any product candidates that succeed 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 revenue. 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 development efforts entail 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 expect to incur substantial losses for the foreseeable future.

For the years ended December 31, 2025 and 2024, our net losses were $161.2 million and $77.6 million, respectively. As of December 31, 2025 and 2024, we had an accumulated deficit of $360.5 million and $199.4 million, respectively. Substantially all of our losses have resulted from expenses incurred in connection with the development of our platform, research and development, clinical trials and from general and administrative costs associated with our operations. We expect to incur substantial losses for the foreseeable future, and we expect these losses to increase as we continue the development of our product candidates. We anticipate that our expenses will increase substantially if, and as, we:

- conduct clinical trials for ML-007C-MA and ML-004 and advance our preclinical programs;
- seek regulatory approvals for our product candidates that complete clinical trials or any future product candidates;
- commercialize our current product candidates or any future product candidates, if approved;
- oversee, maintain and expand our external manufacturing relationships;
- attract, hire and retain qualified personnel;
- protect, maintain, enforce and defend our rights in our intellectual property portfolio;
- 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; and
- incur additional costs, including legal, accounting and other expenses, associated with operating as a newly 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 are able to obtain regulatory approval for, and successfully commercialize, one of our product candidates for either our initial or potential additional indications or any other product candidates we may develop.

Successful commercialization will require achievement of many key milestones, including demonstrating safety and efficacy in clinical trials, obtaining regulatory, including marketing, 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. Due to the uncertainties and risks associated with these

activities, we are unable to accurately and precisely predict the timing and amount of revenue we may generate, the extent of any further losses we may experience and if or when we might achieve profitability. We may never succeed in these activities and, even if we do, we may never generate revenue that is 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 additional delays in completing our clinical trials or the development of any of our product candidates.

Even if we succeed in commercializing one or more product candidates, we expect to incur substantial development costs and other expenditures to develop and market additional product candidates. We may also encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue in the future. Our prior losses and expected future losses have had and will continue to have a material adverse effect on our stockholders' equity and working capital and may have a material adverse effect on our business, financial condition, results of operations and prospects. Our failure to become and remain profitable may decrease the market price of our common stock and could impair our ability to raise capital, expand our business, diversify our product portfolio or continue our operations.

We will require substantial additional financing to achieve our goals, and failure to obtain additional capital when needed, or on acceptable terms, 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 future product candidates, to seek regulatory approvals for our product candidates and to launch and commercialize any products if we receive regulatory approval. As of December 31, 2025, we had $453.1 million of cash, cash equivalents and investments. Based on our current operational plans and assumptions, we believe our existing cash, cash equivalents and investments will be sufficient to fund our operations through 2027. This estimate is based on assumptions that may prove to be wrong, and our future capital requirements and the period through which our existing resources will support our operations may vary significantly from what we expect. We will require additional capital in order to complete clinical development of any of our current programs, and our 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 candidates is 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;
- 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 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;
- the effectiveness of our platform in identifying additional targets and indications of interest;
- 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 of our product candidates for which we receive marketing approval;

- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- expenses to attract, hire and retain skilled personnel;
- 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;
- addressing any potential supply chain interruptions or delays;
- our ability to mitigate the impact of adverse macroeconomic or geopolitical conditions, including the ongoing conflicts between Ukraine and Russia and in the Middle East, inflation, tariffs and fluctuations in interest rates or other factors, 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 business, 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. Our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions, including fluctuations in interest rates, inflation and concerns of a recession in the United States or other major markets, potential tariffs and disruptions to and volatility in the credit and financial markets in the United States and worldwide. Weakness and volatility in the capital markets and the economy in general could also increase our costs of borrowing. Such funds, if raised, may not be sufficient to enable us to continue to implement our long-term business strategy. 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. Furthermore, 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 may adversely affect your rights as a holder of our common stock. See "—Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates," below. 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 materially and adversely impact our business, financial condition, results of operations and prospects.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

Until we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of public or private equity offerings and debt financings or other sources, such as potential collaboration agreements, strategic alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted and the terms of such securities may include liquidation or other preferences that adversely affect your rights as a common stockholder.

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 may be required to significantly 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. Additionally, these circumstances could require that we undertake workforce reductions or restructuring activities in the future. Any of the above events could materially and adversely affect our business, financial condition, results of operations and prospects and cause the price of our common stock to decline.

Risks Related to the Design, Development, Approval and Commercialization of our Product Candidates

If we are unable to successfully identify, develop and commercialize any product candidates, or experience significant delays in doing so, our business, financial condition, results of operations and prospects will be materially and adversely affected.

Our ability to generate revenue from sales of any of our approved product candidates, which we do not expect will occur for at least the next several years, depends heavily on the successful identification, development, regulatory approval and eventual commercialization of product candidates, which may never occur. We have never generated revenue from sales of any products, and we may never be able to develop, obtain regulatory approval for or commercialize, a marketable product. All of our product candidates will require significant clinical development, regulatory approval, establishment of sufficient manufacturing supply, including commercial manufacturing supply, and may require us to build a commercial organization and make substantial investment and significant marketing efforts before we generate any revenue from product sales. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our product candidates.

The successful development of our product candidates will depend on several factors, including the following:

- successful and timely completion of preclinical studies and gaining agreement on the design, endpoints and implementation of clinical trials with the FDA or any comparable foreign regulatory authority;
- sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials;
- receiving regulatory approvals or authorizations for conducting future clinical trials;
- initiation and successful patient enrollment in, and completion of, clinical trials on a timely basis;
- our ability to demonstrate to the satisfaction of the FDA or any comparable foreign regulatory authority that the applicable product candidate is safe and effective as for its intended uses;
- our ability to demonstrate to the satisfaction of the FDA or any comparable foreign regulatory authority that the applicable product candidate's risk-benefit ratio for its proposed indication is acceptable;
- timely receipt of marketing approvals for our product candidates from applicable regulatory authorities;
- the extent of any required post-marketing approval commitments to applicable regulatory authorities;
- establishing and scaling up, either alone or with third-party manufacturers, manufacturing capabilities of clinical supply for our clinical trials and commercial manufacturing, if any of our product candidates are approved;
- effectively competing with other therapies available on the market or in development; and
- successfully identifying and developing, acquiring or in-licensing additional product candidates to expand our pipeline.

Many of these factors are beyond our control, and it is possible that none of our product candidates will ever obtain regulatory approval even if we expend substantial time and resources seeking such approval. If we experience significant delays or are otherwise unable to successfully commercialize our product candidates, our business, financial condition, results of operations and prospects could be materially and adversely affected.

Additionally, clinical or regulatory setbacks to other companies developing similar products or within adjacent fields may impact the clinical development of and regulatory pathway for our current or future product candidates or may negatively impact the perceptions of value or risk of our technologies.

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

We are not permitted to commercialize, market, promote or sell any product candidate in the United States without obtaining regulatory approval from the FDA. Foreign regulatory authorities, such as the European Medicines Agency, impose similar requirements. The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable, but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including substantial discretion of the regulatory authorities. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. To date, we have not submitted a New Drug Application, or NDA, to the FDA or similar drug approval submissions to comparable foreign regulatory authorities for any of our product candidates. We must complete additional preclinical or nonclinical studies and clinical trials to demonstrate the safety and efficacy of our product candidates in humans before we will be able to obtain these approvals.

Clinical testing is expensive, difficult to design and implement, can take many years to complete and is inherently uncertain as to outcome. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. Clinical development is susceptible to the risk of failure inherent at any stage of development, including failure to demonstrate efficacy in a clinical trial or across a broad population of patients, the occurrence of AEs that are severe or medically or commercially unacceptable, failure to comply with protocols or applicable regulatory requirements and determination by the FDA or any comparable foreign regulatory authority that a product candidate may not continue development or is not approvable. Additionally, given that ML-007C-MA is a fixed-combination drug product, we will need to demonstrate that each component of the product candidate makes a contribution to the claimed effects (safety and tolerability) and the dosage of each component (amount, frequency, duration) in combination is safe and effective for a significant patient population requiring such concurrent therapy as defined in the labeling for the drug. In addition, if the PAC we have selected has regulatory challenges, it may adversely impact the development of our fixed-combination drug product. It is possible that even if one of our product candidates has a beneficial effect, that effect will not be detected during clinical evaluation as a result of one or more of a variety of factors, including the size, duration, design, measurements, conduct or analysis of our clinical trials. Conversely, as a result of the same factors, our clinical trials may indicate an apparent positive effect of one of our product candidates that is greater than the actual positive effect, if any. Similarly, in our clinical trials we may fail to detect toxicity of or intolerability caused by one of our product candidates, or mistakenly believe that our product candidates are toxic or not well tolerated when that is not, in fact, the case. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate.

Our current and future product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree as to the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from clinical trials or preclinical studies;
- the FDA or comparable foreign regulatory authorities may disagree with our study design, including inclusion or exclusion criteria, in our clinical trials;

- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA to the FDA or other submission or to obtain regulatory approval in the United States, the European Union or elsewhere;
- the FDA or comparable foreign regulatory authorities may find deficiencies with or fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy approval process as well as the unpredictability of clinical trial results may result in our failing to obtain regulatory approval to market any product candidate we develop, which would significantly harm our business, financial condition, results of operations and prospects. There is no assurance that the endpoints and trial designs used for the approval of currently approved drugs will be acceptable for future approvals, including for those of our product candidates. For example, in 2024, the FDA published revised draft guidance for drug development in early AD with a recommendation to use consensus diagnostic criteria intended to establish the true biological presence of AD, rather than criteria based on syndromic or other definitions. The FDA and other comparable foreign authorities have substantial discretion in the approval process and determining when or whether regulatory approval will be obtained for any product candidate that we develop. Even if we believe the data collected from our current or future clinical trials of our product candidates are promising, such data may not be sufficient to support approval by the FDA or any other regulatory authority.

In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates, and therefore materially and adversely impact our business, financial condition, results of operations and prospects.

We may incur unexpected costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

To obtain the requisite regulatory approvals to commercialize any of our product candidates, we must demonstrate through extensive preclinical studies and clinical trials that our product candidates are safe and effective in humans. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process and our future clinical trials may not be successful.

We may experience delays in initiating or completing our clinical trials or preclinical studies. We may also experience numerous unforeseen events during our clinical trials that could delay or prevent our ability to receive marketing approval or commercialize the product candidates we develop, including:

- regulators, independent institutional review boards, or IRBs, or other reviewing bodies may not authorize us or our investigators to commence a clinical trial, or to conduct or continue a clinical trial, at a prospective or existing trial site;
- we may not reach agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- the number of subjects or patients required for clinical trials may be larger than we anticipate, enrollment in these clinical trials may be insufficient or slower than we anticipate, the number of competing clinical trials being conducted at any given time may be high and result in fewer available patients for any given clinical trial or patients may drop out of clinical trials at a higher rate than we anticipate;

- our third-party contractors, including those manufacturing our product candidates or conducting clinical trials on our behalf, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we may have to amend a clinical trial protocol submitted to regulatory authorities or conduct additional studies to reflect changes in regulatory requirements or guidance, which we may be required to resubmit to an IRB and regulatory authorities for re-examination;
- regulators, IRBs or other reviewing bodies may fail to approve or subsequently find fault with the manufacturing processes or facilities of third-party manufacturers with which we enter into agreement for clinical and commercial supplies, the supply or quality of product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient, inadequate or not available at an acceptable cost or we may experience interruptions in supply; and
- the potential for approval policies or regulations of the FDA or the applicable foreign regulatory agencies to significantly change in a manner rendering our clinical data insufficient for approval.

Delays, including delays caused by the above factors, can be costly and could negatively affect our ability to complete a clinical trial or obtain timely marketing approvals. We do not know whether any of our planned preclinical studies or clinical trials will begin on a timely basis or at all, will need to be restructured or will be completed on schedule, or at all. For example, in January 2022, our Phase 2 ML-004 clinical trial was placed on a partial clinical hold by the FDA with respect to the enrollment of adolescents pending submission of safety data from the adult cohorts to the FDA. This partial clinical hold was removed by the FDA in October 2024. In addition, our IND for ML-007C-MA was put on clinical hold by the FDA in May 2024 due to nonclinical findings associated with a single-agent animal study for ML-007. This hold was lifted in July 2024 after the FDA's review of additional clinical and nonclinical data, and we initiated the Phase 2 trials in the United States for ADP and schizophrenia in May 2025 and June 2025, respectively. We cannot assure you that our existing and future INDs will not be subject to additional clinical holds, whether partial or full. If we are not able to complete successful clinical trials on the schedule we expect, we will not be able to obtain regulatory approval, and will not be able to commercialize our product candidates, on the timelines we expect. Our product candidate development costs will also increase if we experience delays in testing or regulatory approvals, and we may be required to obtain additional funds to complete clinical trials. We cannot assure you that our clinical trials will begin as planned or be completed on schedule, if at all, or that we will not need to restructure our trials after they have begun. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates, which may harm our business and results of operations. In addition, many of the factors that cause, or lead to, delays of clinical trials may ultimately lead to the denial of regulatory approval of our product candidates, which may materially and adversely affect our business, financial condition, results of operations and prospects.

If we encounter difficulties enrolling patients in our ongoing or planned clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

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

Patient enrollment is affected by many factors, including:

- the patient eligibility criteria defined in the protocol;
- the size of the patient population required for analysis of the trial's primary endpoints;
- the proximity of patients to trial sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- competing clinical trials;

- 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 drugs that may be approved for the indications that we are investigating;
- our ability to obtain and maintain patient consents; and
- the risk that patients enrolled in clinical trials will drop out of the trials before completion.

Our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition may reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which may reduce the number of patients who are available for our clinical trials in such clinical trial site.

Our inability to enroll a sufficient number of patients for our clinical trials could result in significant delays or might require us to abandon one or more clinical trials altogether. Our clinical trials may face delays if we are required to restrict enrollment to a more selective group of participants based on age, disease severity or biomarkers, among other factors. For example, in 2024 the FDA published revised draft guidance for drug development in early AD with a recommendation to use consensus diagnostic criteria intended to establish the true biological presence of AD, rather than criteria based on syndromic or other definitions. Delays in patient enrollment may result in increased costs, affect the timing or outcome of the planned clinical trials, product candidate development and approval process, prevent completion of these trials and jeopardize our ability to seek and obtain the regulatory approval required to commence product sales and generate revenue, which could adversely affect our ability to advance the development of our product candidates, cause the value of our company to decline and limit our ability to obtain additional financing, if needed.

Obtaining authorization from regulatory authorities for clinical trials in adolescents and pediatric patients may require longer duration of studies than we currently anticipate, which could delay our development programs or preclude us from pursuing approval in the populations for which we are seeking approval.

Pediatric drug development, including with respect to ML-004 for the treatment of adolescents, may require additional trials to determine safe dosing and long-term safety. These additional trials may require investment of significant additional resources beyond those required for regulatory approval of the drugs in adults. We cannot guarantee that we will receive regulatory approval to commercialize our product candidates in the pediatric populations or the adult population.

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

We conduct certain clinical trials for our product candidates outside of the United States. The acceptance of data from clinical trials conducted outside the United States or another jurisdiction by the FDA or comparable foreign regulatory authority may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the 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 Good Clinical Practice, or 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. In addition, even where the foreign study data are not intended to serve as the sole basis for approval, the FDA will not accept the data as support for an application for marketing approval unless the study is well designed and well conducted in accordance with GCP regulations and the FDA is able to validate the data from the study through an onsite inspection, if deemed necessary. Many foreign regulatory authorities have similar approval requirements. 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 that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA or any comparable

foreign regulatory authority does not accept such data, it would result in the need for additional trials, which could be costly and time consuming and which may result in current or future product candidates that we may develop not receiving approval for commercialization in the applicable jurisdiction.

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

We have never commercialized a product, and even if any of our product candidates is approved by the appropriate regulatory authorities for marketing and sale, it may nonetheless fail to achieve sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. Many of the indications for our product candidates have well-established standards of care that physicians, patients and payors are familiar with and, in some cases, are available generically. Even if our product candidates are successful in registrational clinical trials, they may not be successful in displacing these current standards of care if we are unable to demonstrate superior efficacy, safety, ease of administration and/or cost-effectiveness. For example, physicians may be reluctant to take their patients off their current medications and switch their treatment regimen to our product candidates. Further, patients often acclimate to the treatment regimen that they are currently taking and do not want to switch unless their physicians recommend switching products or they are required to switch due to lack of coverage and adequate reimbursement. Even if we are able to demonstrate our product candidates' safety and efficacy to the FDA and other regulators, safety or efficacy concerns in the medical community may hinder market acceptance.

Efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources, including management time and financial resources, and may not be successful. If any product candidate is approved but does not achieve an adequate level of market acceptance, we may not generate significant revenue and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and safety of the product;
- the potential advantages of the product compared to competitive therapies;
- the occurrence and severity of any side effects;
- whether the product is designated under physician treatment guidelines as a first-, second- or third-line therapy;
- our ability to offer the product for sale at competitive prices;
- the product's convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try, and of physicians to prescribe, the product;
- limitations or warnings, including distribution or use restrictions contained in the product's approved labeling;
- the strength of our sales, marketing and distribution support, including having sufficient staffing and financial resources;
- changes in the standard of care for the targeted indications for the product; and
- availability and adequacy of coverage and reimbursement from government payors, managed care plans and other third-party payors.

Any failure by one or more of our product candidates that obtains regulatory approval to achieve market acceptance or commercial success would materially and adversely affect our business, financial condition, results of operations and prospects.

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

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

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

Our product candidates may be associated with serious adverse events, undesirable side effects or other properties that could halt their clinical development, prevent their regulatory approval, limit their commercial potential or result in significant negative consequences.

Adverse events or other undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approvals by the FDA or other comparable foreign regulatory authorities.

During the conduct of clinical trials, patients report changes in their health, including illnesses, injuries and discomforts, to their study doctor. Often, it is not possible to determine whether or not the product candidate being studied caused these conditions. It is possible that as we test our product candidates in larger, longer and more extensive clinical trials, or as use of these product candidates becomes more widespread if they receive regulatory approval, illnesses, injuries, discomforts and other adverse events that were observed in previous trials, as well as conditions that did not occur or went undetected in previous trials, will be reported by patients. Many times, side effects are only detectable after investigational products are tested in large-scale clinical trials or, in some cases, after they are made available to patients on a commercial scale following approval. If any serious adverse events occur during clinical development, clinical trials could be suspended or terminated, and our business could be seriously harmed. Treatment-related side effects could also affect patient recruitment and the ability of enrolled patients to complete the trial or result in potential liability claims. Regulatory authorities could order us to cease further development of, or deny approval of, our product candidates. If we are required to delay, suspend or terminate any clinical trial or our development efforts, the commercial prospects of our product candidates may be harmed, and our potential to generate product revenues from them may be delayed or eliminated. Additionally, if one or more of our product candidates receives marketing approval and we or others later identify undesirable side

effects or adverse events caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may suspend, limit or withdraw approvals of such product or seek an injunction against its manufacture or distribution;
- regulatory authorities may require additional warnings on the label, including "boxed" warnings, or issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product;
- we may be required to change the way the product is administered or conduct additional clinical trials or post-approval studies;
- we may be required to create a risk evaluation and mitigation strategy, or REMS, which could include a medication guide outlining the risks of such side effects for distribution to patients;
- we may be subject to fines, injunctions or the imposition of criminal penalties;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of ML-007C-MA, ML-004 or any of our other product candidates, if approved, and could seriously harm our business.

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

As product candidates proceed through preclinical studies to late-stage clinical trials towards potential approval and commercialization, it is common that various aspects of the development program, such as the vendors used to manufacture drug product or manufacturing methods and formulation, are altered along the way 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 candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the materials manufactured using altered processes. Such changes may also require additional testing, FDA notification or FDA approval. This could delay or prevent completion of clinical trials, require conducting bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay or prevent approval of our product candidates and jeopardize our ability to commence sales and generate revenue.

If we 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 candidates are our initial focus, as part of our longer-term growth strategy, we plan to develop other product candidates. In addition to the product candidates in our clinical-stage pipeline, we have additional assets that are in earlier stages of development. We intend to evaluate internal opportunities from our existing product candidates or other potential product candidates and also may choose to in-license or acquire other product candidates 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 applicable 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 that are approved will be manufactured or produced economically, successfully commercialized or widely accepted in the marketplace or be more effective than other commercially available alternatives.

In addition, we intend to devote substantial capital and resources for basic research to discover and identify additional product candidates. These research programs require substantial technical, financial and human resources, whether or not any product candidates are ultimately identified. Our platform 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 candidates 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, either through internal development or licensing or acquisition from third parties, our potential for growth and achieving our strategic objectives may be impaired, and our business, financial condition, results of operations and prospects could be materially and adversely affected.

We may expend our limited resources to pursue a particular product candidate or indication and forego 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 candidates for specific indications that we identify as most likely to succeed in terms of their potential for regulatory approval, unmet need and potential commercial success. As a result, we may forego, delay or explore alternative development strategies, including partnership, spin-off or divestment, of our other product candidates or forego other indications, all of which may prove to have greater commercial potential than the product candidates and indications we pursue.

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 candidates for specific indications may not yield any commercially viable product candidates. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate, including through entering into 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.

We have concentrated our research and development efforts on the treatment of disorders of the central nervous system, a field that faces certain challenges in drug development.

We have focused our research and development efforts on addressing disorders of the CNS. Efforts by biotechnology and pharmaceutical companies in this field have faced certain challenges in drug development historically. For example, we are currently developing ML-007C-MA for the treatment of schizophrenia and ADP, and clinical trials focused on neuropsychiatric diseases such as schizophrenia or ADP 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 placebo effect, which may make it more challenging to isolate the beneficial effects of our product candidates. There can be no guarantee that we will successfully overcome these challenges with our product candidates or that we will not encounter other challenges in the development of our product candidates.

We may in the future seek to engage in strategic transactions to acquire or in-license additional products, product candidates or technologies. If we are unable to realize the benefits from such transactions, it may adversely affect

our ability to develop and commercialize an expanded pipeline of product candidates, negatively impact our cash position, increase our expenses and present significant distractions to our management.

From time to time, we may consider strategic transactions, such as additional collaborations, acquisitions of companies, asset purchases, joint ventures and in-licensing of new products, product candidates or technologies that we believe will complement or augment our existing business. If we acquire assets with promising markets or technologies, we may not be able to realize the benefit of acquiring such assets if we are not able to successfully integrate them with our existing technologies. We may encounter numerous difficulties in developing, testing, manufacturing and marketing any new products resulting from a strategic acquisition that delay or prevent us from realizing their expected benefits or enhancing our business.

Following any such strategic transaction, we may not achieve any expected synergies to justify the transaction. For example, such transactions may require us to incur non-recurring or other charges, increase our near-term and long-term expenditures, experience significant integration or implementation challenges or disrupt our management or business. These transactions would entail numerous operational and financial risks, including exposure to unknown liabilities; disruption of our business and diversion of our management's time and attention in order to manage a collaboration or develop acquired products, product candidates or technologies; incurrence of substantial debt or dilutive issuances of equity securities to pay transaction consideration or costs; higher-than-expected acquisition or integration costs, write-downs of assets or goodwill or impairment charges; increased amortization expenses; difficulty and cost in facilitating the transaction or combining the operations and personnel of any acquired business; impairment of relationships with key suppliers, manufacturers or customers of any acquired business due to changes in management and ownership; and the inability to retain key employees of any acquired business.

Accordingly, although there can be no assurance that we will undertake or successfully complete any transactions of the nature described above, any transactions that we do complete may be subject to the foregoing or other risks and could have a material and adverse effect on our business, financial condition, results of operations and prospects. Conversely, any failure to enter any strategic transaction that would be beneficial to us could delay the development and potential commercialization of our product candidates and could have a negative impact on the competitiveness of any product candidate that reaches market.

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 from obtaining approvals for the commercialization of our product candidates.

Any product candidate we develop, and the activities associated with its development and commercialization, including its design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, is subject to comprehensive regulation by the FDA and other regulatory authorities in the United States and by comparable authorities in other countries. 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 it is possible that none of the product candidates we are developing or may seek to develop in the future will ever obtain regulatory approval.

We have no experience in submitting and supporting the applications necessary to gain marketing approvals and expect to rely on third-party CROs or regulatory 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. 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 its obtaining marketing approval or prevent or limit commercial use.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive, may take many years if additional clinical trials are required, 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. 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. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. Any marketing approval that we may ultimately obtain could be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

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 may be harmed, and our ability to generate revenue will be materially impaired.

We may face uncertainty related to pricing, coverage and reimbursement for our product candidates.

Successful sales of our product candidates in the U.S. market, if approved, will depend, in part, on the extent to which our products will be covered by third-party payors, such as government health programs like Medicaid and Medicare, or private health insurance (including managed care plans). These third-party payors are increasingly limiting coverage and/or reducing reimbursements for medical products and services. A third-party payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a drug product does not ensure that other payors will also provide coverage for the drug product. Coverage policies and third-party payor reimbursement rates may change at any time. Third-party payors are increasingly reducing coverage for medical drugs and services and implementing measures to control utilization of drugs (such as requiring prior authorization for coverage). Patient copays can be significant and may vary among products within a class depending upon the formulary status of an agent with a particular payor. Inconsistencies in formulary status across state Medicaid plans and commercial payors may result in coverage gaps in some geographical areas.

Additionally, the containment of healthcare costs has become a priority of federal and state governments, and the prices of drugs have been a focus in this effort. The U.S. government, state legislatures, and foreign governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on coverage and requirements for substitution of generic drugs. Adoption or expansion of price controls and cost-containment measures could further limit our net revenue and results. Decreases in third-party coverage for our product candidates, if approved, or a decision by a third-party payor to not cover our product candidates could have a material adverse effect on our sales, results of operations, and financial condition. If we are unable to obtain adequate levels of reimbursement, our ability to successfully market and sell any product candidates if approved will be harmed.

General legislative cost control measures may also affect reimbursement for our products. If we obtain approval to market a product candidate in the United States, we may be subject to spending reductions affecting Medicare, Medicaid or other publicly funded or subsidized health programs and/or significant taxes or fees.

The market for our current or future product candidates may be smaller than we expect.

Our estimates of the potential market opportunity for ML-007C-MA for the treatment of patients with schizophrenia and ADP, ML-004 for ASD and any other product candidates we may develop include several key assumptions based on our industry knowledge, industry publications and third-party research reports. There can be no assurance that any of these assumptions are, or will remain, accurate. If the actual markets for ML-007C-MA or ML-004 for these or other indications, or for any other product candidate we may develop, are smaller than we expect, our revenue, if any, may be limited and it may be more difficult for us to achieve or maintain profitability.

Competitive products may reduce or eliminate the commercial opportunity for our product candidates for our current or future indications. If our competitors develop technologies or product candidates more rapidly than we

do, or their technologies or product candidates are more effective or safer than ours, our ability to develop and successfully commercialize our product candidates may be adversely affected.

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on intellectual property. While we believe our product candidates, approach, knowledge, experience and scientific resources provide us with competitive advantages, we face potential competition from many different sources, including pharmaceutical and biotechnology companies, academic institutions and governmental agencies, as well as public and private research institutions. Any product candidates that we successfully develop and commercialize will compete with approved treatment options, off-label therapies and new therapies that may become available in the future.

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

Our commercial opportunity could be reduced or eliminated if competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Competitors also may obtain FDA or other regulatory approval for their products more rapidly or earlier than us, which could result in our competitors establishing a strong market position before we are able to enter the market. Additionally, technologies developed by our competitors may render our potential product candidates uneconomical or obsolete, and we may not be successful in marketing our product candidates against competitors.

We are developing ML-007C-MA for the treatment of schizophrenia, ADP and other potential indications. We may face competition from typical and atypical antipsychotic treatments that work primarily by inhibiting dopamine and serotonin receptors. In addition, we are aware of several product candidates in clinical development that are designed to modulate muscarinic receptors, such as Cobenfy (also known as KarXT), which is marketed for the treatment of schizophrenia and being developed for additional indications by Bristol-Myers Squibb Company; emraclidine, which is being developed by AbbVie Inc.; direclidine, NBI-'570 and NBI-'567, which are being developed by Neurocrine Biosciences, Inc.; and NMRA-861 and NMRA-898, which are being developed by Neumora Therapeutics, Inc. and Syremis Therapeutics Ltd.

We may also face competition from other companies developing product candidates to address schizophrenia, ADP and other relevant indications that are designed to modulate other non-muscarinic receptors, including ACP-204, which is being developed by Acadia Pharmaceuticals, Inc. We may also face competition from other companies developing product candidates to address agitation or other behavioral symptoms associated with Alzheimer's disease.

We are developing ML-004 for the treatment of ASD. There are currently no FDA-approved pharmaceutical treatments for social communication deficits in ASD. In the treatment of the irritability symptoms associated with ASD, we may face competition from ABILIFY, marketed by Otsuka Pharmaceutical Co., Ltd., and RISPERDAL, marketed by Johnson & Johnson, as well as from generic forms of those drugs that are being marketed and sold.

Even if we obtain FDA approval of any of our product candidates in the United States, we may never obtain approval for or commercialize any of them in any other jurisdiction, which would limit our ability to realize their full market potential.

In order to market any products in any particular jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a country-by-country basis regarding safety and efficacy.

Approval by the FDA in the United States does not ensure approval by regulatory authorities in other countries or jurisdictions. However, the failure to obtain approval in one jurisdiction may negatively impact our ability to obtain approval elsewhere. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries and regulatory approval in one country does not guarantee regulatory approval in any other country.

Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approval could result in difficulties and increased costs for us and require additional preclinical studies or clinical trials which could be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. We do not have any product candidates approved for sale in any jurisdiction, including in international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required 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 any product we develop will be unrealized.

If we obtain approval to commercialize any products outside of the United States, we could experience a variety of risks associated with international operations that could adversely affect our business.

If any of our current or future product candidates are approved for commercialization, we may seek to enter into agreements with third parties to market them in certain jurisdictions outside the United States. We expect that we would be subject to additional risks related to international pharmaceutical operations, including:

- different regulatory requirements for drug and companion diagnostic approvals and rules governing drug and companion diagnostic commercialization in foreign countries;
- reduced protection for intellectual property rights;
- foreign reimbursement, pricing and insurance regimes;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation or impacts related to tariffs, fluctuating interest rates or other factors, or political instability in particular foreign economies and markets;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- business interruptions resulting from geopolitical actions, including war and terrorism or natural disasters including earthquakes, typhoons, floods and fires, or from economic or political instability;
- greater difficulty with enforcing our contracts;
- potential noncompliance with the U.S. Foreign Corrupt Practices Act, or FCPA, the U.K. Bribery Act 2010 and similar anti-bribery and anticorruption laws in other jurisdictions; and
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad.

We have no prior experience in these areas. In addition, there are complex regulatory, tax, labor and other legal requirements imposed by individual countries in Europe with which we will need to comply. If we are unable to successfully manage the challenges of international expansion and operations, our business, financial condition, results of operations and prospects could be materially and adversely affected.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop, which could adversely affect our business, financial condition, results of operations and prospects.

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if we commercialize any products that we may develop. For example, we may be sued if our product candidates cause or are perceived to cause injury or are found to be

otherwise unsuitable during clinical trials, manufacturing, marketing or sale. Any such product liability claims could include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims also could be asserted under state consumer protection acts. Product liability claims could delay or prevent completion of our development programs. If we cannot successfully defend ourselves against any claims that our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- inability to bring a product candidate to market;
- decreased demand for any product candidates or products that we may develop;
- injury to our reputation and significant negative media attention;
- initiation of investigations by U.S. and foreign regulators;
- withdrawal of clinical trial participants;
- significant time and costs to defend the related litigation;
- diversion of management and resources from our business operations;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- reduced resources of our management to pursue our business strategy;
- the inability to commercialize any products that we may develop; and
- decline in our stock price.

Our current product liability insurance coverage for the United States and certain other jurisdictions may not be adequate to cover all liabilities that we may incur. We likely will need to increase our insurance coverage as we expand our clinical trials or if we commence commercialization of ML-007C-MA, ML-004 or our future product candidates. Insurance coverage is increasingly expensive. Our insurance policies also may have various deductibles and exclusions, and we may be subject to a product liability claim for which we have no coverage. We may need to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, enforcing such indemnification provisions may cause diversion of management's time and our resources and such indemnification may not be available or adequate should any claim arise. A successful product liability claim or series of claims brought against us could decrease our cash and cash equivalents and materially and adversely affect our business, results of operations, financial condition and prospects.

Risks Related to Government Regulation

Even if we receive regulatory approval of our current or future product candidates, 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 candidates.

Any product candidate for which we obtain marketing approval will be subject to ongoing regulatory requirements for, among other things, manufacturing processes, submission of post-approval clinical data and safety information, labeling, packaging, distribution, adverse event reporting, storage, recordkeeping, export, import, advertising, promotional activities and product tracking and tracing. These requirements include submissions of safety and other post-marketing information and reports, establishment registration and drug listing requirements, continued compliance with Good Manufacturing Practice, or cGMP, regulations relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the

distribution of samples to physicians and recordkeeping and GCP regulations for any clinical trials that we conduct post-approval.

In addition, later discovery of previously unknown AEs or other problems with our products, manufacturers or manufacturing processes, including AEs of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes or failure to comply with regulatory requirements, may yield various results, including:

- restrictions on manufacturing such products;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning or untitled letters or holds on clinical trials;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- fines, restitution or disgorgement of profits or revenue;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of our products;
- product seizure or detention; or
- injunctions or the imposition of civil or criminal penalties.

The FDA's policies, and the policies of foreign regulatory agencies, may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates.

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, executive orders or other actions could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine oversight activities such as implementing statutes through rulemaking, issuance of guidance and review and approval of marketing applications. If such executive actions were to impose restrictions on the FDA's ability to engage in oversight and implementation activities in the normal course, our business could be negatively impacted. In addition, the U.S. Supreme Court's June 2024 decision in *Loper Bright Enterprises v. Raimondo* overturned the longstanding Chevron doctrine, under which courts were required to give deference to regulatory agencies' reasonable interpretations of ambiguous federal statutes. The *Loper* decision could result in additional legal challenges to regulations and decisions issued by federal agencies, including the FDA, on which we rely. Any such legal challenges, if successful, could have a material impact on our business. Additionally, the *Loper* decision may result in increased regulatory uncertainty, inconsistent judicial interpretations, and other impacts to the agency rulemaking process, any of which could adversely impact our business and operations. 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 which would materially and adversely affect our business, financial condition, results of operations and prospects.

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

The FDA strictly regulates marketing, labeling, advertising and promotion of prescription drugs. These regulations include standards and restrictions for direct-to-consumer advertising, industry-sponsored scientific and educational activities and promotional activities involving the internet and off-label promotion. Any regulatory approval that the FDA grants is limited to those specific diseases and indications for which a product is deemed to be safe and effective by FDA.

While physicians in the United States may choose, and are generally permitted, to prescribe drugs for uses that are not described in the product's labeling and for uses that differ from those tested in clinical trials and approved by the regulatory authorities, our ability to promote the products is narrowly limited to those indications that are specifically approved by the FDA. These "off-label" uses are common across medical specialties and may constitute an appropriate treatment for some patients in varied circumstances.

Regulatory authorities in the United States generally do not regulate the behavior of physicians in their choice of treatments. Regulatory authorities do, however, restrict communications by pharmaceutical companies regarding off-label use. Although recent court decisions suggest that certain off-label promotional activities may be protected under the First Amendment, the scope of any such protection is unclear. If our promotional activities fail to comply with the FDA's regulations or guidelines, we may be subject to warnings from, or enforcement action by, these authorities. In addition, our failure to follow FDA rules and guidelines relating to promotion and advertising may cause the FDA to issue warning letters or untitled letters, bring an enforcement action against us, suspend or withdraw an approved product from the market, require a recall or institute fines or civil penalties or could result in disgorgement of money, operating restrictions, injunctions or criminal prosecution, any of which could harm our reputation and our business.

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

The ability of the FDA and other government agencies 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, a government agency's ability to hire and retain key personnel and accept the payment of user fees and other events that may otherwise affect the agency's ability to perform routine functions. Average review times at the FDA and other government agencies have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new drugs or modifications to approved drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, in recent years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical employees and stop critical activities. In addition, the current U.S. presidential administration has issued certain policies and executive orders directed towards reducing the employee headcount and costs associated with U.S. administrative agencies, including the FDA, and it remains unclear the degree to which these efforts may limit or otherwise adversely affect the FDA's ability to conduct routine activities.

Separately, in response to the COVID-19 pandemic, the FDA postponed most inspections of domestic and foreign manufacturing facilities at various points. If any future prolonged government shutdown occurs, or if renewed global health concerns, funding shortages or staffing limitations prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

If the FDA does not conclude that certain of our product candidates satisfy the requirements for the Section 505(b)(2) regulatory approval pathway, or if the requirements for such product candidates under Section 505(b)(2) are not as we expect, the approval pathway for those product candidates will likely take significantly longer, cost significantly more and entail significantly greater complications and risks than anticipated and in either case may not be successful.

We are developing a proprietary product candidate for which we may seek FDA approval through the Section 505(b)(2) regulatory pathway. The Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Amendments, added Section 505(b)(2) to the Federal Food, Drug and Cosmetic Act, or FDCA. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies that were not conducted by or for the applicant and for which the applicant has not obtained a right of

reference. Section 505(b)(2), if applicable to us under the FDCA, would allow an NDA we submit to FDA to rely in part on data in the public domain or the FDA's prior conclusions regarding the safety and effectiveness of approved compounds, which could expedite the development program for our product candidates by potentially decreasing the amount of clinical data that we would need to generate in order to obtain FDA approval. If the FDA does not allow us to pursue the Section 505(b)(2) regulatory pathway as anticipated, we may need to conduct additional clinical trials, provide additional data and information and meet additional standards for regulatory approval. If this were to occur, the time and financial resources required to obtain FDA approval for these product candidates, and complications and risks associated with these product candidates, would likely substantially increase. We could need to obtain more additional funding, which could result in significant dilution to the ownership interests of our then existing stockholders to the extent we issue equity securities or convertible debt. We cannot assure you that we would be able to obtain such additional financing on terms acceptable to us, if at all. Moreover, inability to pursue the Section 505(b)(2) regulatory pathway could result in new competitive products reaching the market more quickly than our product candidate, which would likely materially adversely impact our competitive position and prospects. Even if we are allowed to pursue the Section 505(b)(2) regulatory pathway, we cannot assure you that our product candidate will receive the requisite approvals for commercialization.

In addition, notwithstanding the approval of a number of products by the FDA under Section 505(b)(2) over the last few years, certain brand-name pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2). If the FDA's interpretation of Section 505(b)(2) is successfully challenged, the FDA may change its 505(b)(2) policies and practices, which could delay or even prevent the FDA from approving any NDA that we submit under Section 505(b)(2). In addition, the pharmaceutical industry is highly competitive, and Section 505(b)(2) NDAs are subject to special requirements designed to protect the patent rights of sponsors of previously approved drugs that are referenced in a Section 505(b)(2) NDA. These requirements may give rise to patent litigation and mandatory delays in approval of our NDAs for up to 30 months or longer depending on the outcome of any litigation. It is not uncommon for a manufacturer of an approved product to file a citizen petition with the FDA seeking to delay approval of, or impose additional approval requirements for, pending competing products. If successful, such petitions can significantly delay, or even prevent, the approval of the new product. However, even if the FDA ultimately denies such a petition, the FDA may substantially delay approval while it considers and responds to the petition. In addition, even if we are able to utilize the Section 505(b)(2) regulatory pathway, there is no guarantee this would ultimately lead to accelerated product development or earlier approval.

Moreover, even if our product candidate is approved under Section 505(b)(2), the approval may be subject to limitations on the indicated uses for which the products may be marketed or to other conditions of approval, or may contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the products.

Current and future healthcare reform legislation or regulation may increase the difficulty and cost for us to obtain coverage for and commercialize our product candidates and may adversely affect the prices we may set.

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

For example, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the ACA, was enacted in the United States in 2010 and substantially changed the way healthcare is financed by both the government and private insurers. Since the ACA's passage, legislative changes to the ACA have been proposed and adopted. For example, on July 4, 2025, the annual reconciliation bill, the "One Big Beautiful Bill Act," or OBBBA, was signed into law, which narrowed access to ACA marketplace exchange enrollment and declined to extend the ACA's enhanced advanced premium tax credits, set to expire in 2025, which, among other provisions in the law, are anticipated to reduce the number of Americans with health insurance. The OBBBA is also 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, if approved, or additional pricing pressures.

Additionally, under the sequestration required by the Budget Control Act of 2011, beginning April 1, 2013, Medicare payments to providers were reduced, which will remain in effect through 2032 unless additional Congressional action is taken.

The current Presidential administration is pursuing policies to reduce regulations and expenditures across the federal government, 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, patients in the United States 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 actions and proposals include, for example: (1) directing agencies to reduce workforce and cut programs; (2) directing HHS and other agencies to lower prescription drug costs through a variety of initiatives, including by improving upon the Medicare Drug Price Negotiation Program and establishing most-favored-nation pricing for pharmaceutical products; (3) imposing tariffs of 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. Additionally, in its June 2024 decision in *Loper Bright Enterprises v. Raimondo*, the U.S. Supreme Court 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, among others, impact the drug approval process and make changes to modify the Medicare Drug Price Negotiation Program.

At the state level, legislatures and state agencies have increasingly passed legislation and implemented regulations that are designed to control pharmaceutical and biological product pricing, including price or reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, that are designed to encourage importation from other countries and bulk purchasing. Some states have enacted legislation creating so-called prescription drug affordability boards, which ultimately may attempt to impose price limits on certain drugs in these states, while some states are also seeking to implement general, across-the-board price caps for pharmaceuticals, or are seeking to regulate drug distribution. Legally mandated price controls on payment amounts by third-party payors or other restrictions could materially and adversely impact our business, financial condition, results of operations and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. Any of these actions could reduce the ultimate demand for our product candidates, if approved, or put pressure on our product pricing, which 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 more rigorous coverage criteria and 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 product.

If we or our third-party manufacturers and suppliers fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on our business, financial condition, results of operations and prospects.

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. Although we do not currently manufacture our drug products or product candidates on site, our research and development activities do involve the use of biological and hazardous materials and produce hazardous waste products at small quantities. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by our third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials or other work-related injuries, which includes coverage for biological hazardous waste and medical hazardous waste or radioactive contamination, this insurance may not provide adequate coverage against potential liabilities.

We are subject to various U.S. federal, state and foreign healthcare laws and regulations, which could increase compliance costs, and our failure to comply with these laws and regulations could harm our reputation, subject us to significant fines and liability or otherwise adversely affect our business.

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers subject us to broadly applicable foreign, federal and state fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute any products for which we obtain regulatory approval. Such laws include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or providing any remuneration (including any kickback, bribe or certain rebates), directly or indirectly, overtly or covertly, in cash or in kind, in return for, either the referral of an individual or the purchase, lease or order or arranging for or recommending the purchase, lease or order 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 Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation;
- the federal false claims laws, including the civil False Claims Act, and civil monetary penalties laws, which prohibit, among other things, individuals or entities from knowingly presenting or causing to be presented, to the federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim or from knowingly making or causing to be made a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing, or covering up a material fact or making any materially false statement, in connection with the delivery of or payment for, healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, which 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;
- the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the CMS information related to payments and other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician practitioners (physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiology assistants and certified nurse-midwives) and teaching hospitals and other healthcare providers, as well as ownership and investment interests held by such healthcare professionals and their immediate family members; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; some state laws that require certain regulatory licenses to manufacture or distribute our products commercially and/or the registration of pharmaceutical sales representatives in the jurisdiction; some state laws that require biopharmaceutical companies to comply with the biopharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and some state laws that require biopharmaceutical companies to report information on the pricing of certain drug products.

Efforts to ensure that our current and future business arrangements and those with third parties will comply with applicable healthcare and privacy laws and regulations will involve ongoing substantial costs. It is possible that governmental authorities will conclude that our business practices, including certain consulting agreements and advisory board agreements we have entered into with physicians who are paid, in part, in the form of stock or stock options, may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. Due to the breadth of these laws, the narrowness of statutory exceptions and regulatory safe harbors available, and the range of interpretations to which they are subject, it is possible that some of our current or future practices might be challenged under one or more of these laws. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government-funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our operations. Defending against any such actions can be costly and time consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. Further, if any of the physicians or other healthcare providers or entities with whom we expect to do business are found not to be in compliance with applicable laws or regulations, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government-funded healthcare programs.

We are subject to stringent and evolving U.S. and foreign laws, regulations and rules, contractual obligations, industry standards, policies and other obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation (including

class claims) 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 collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit and share (collectively, process) personal data and other sensitive information, including proprietary and confidential business data, trade secrets, intellectual property, sensitive third-party data, business plans, transactions, financial information and data we collect about trial participants in connection with clinical trials (collectively, sensitive data).

Our 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. For example, HIPAA, as amended by HITECH, imposes specific requirements relating to the privacy, security and transmission of individually identifiable protected health information.

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).

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. As applicable, such rights include the right to access, correct or delete certain personal data, and to opt-out of certain data processing activities, such as targeted advertising, profiling and automated decision-making. The exercise of these rights may impact our business and ability to provide our products and services. Certain states also impose stricter requirements for processing certain personal data, including sensitive information, such as conducting data privacy impact assessments. These state laws allow for statutory fines for noncompliance. For example, the California Consumer Privacy Act of 2018, or CCPA, applies to personal data of consumers, business representatives and employees who are California residents and requires businesses to provide specific disclosures in privacy notices and honor requests of such individuals to exercise certain privacy rights. The CCPA provides for fines and allows private litigants affected by certain data breaches to recover significant statutory damages. Although the CCPA exempts some data processed in the context of clinical trials, the CCPA increases compliance costs and potential liability with respect to other personal data we maintain about California residents.

Similar laws are being considered in several other states, as well as at the federal and local levels, and we expect more states to pass similar laws in the future. While these states, like the CCPA, also exempt some data processed in the context of clinical trials, these developments may further complicate compliance efforts and increase legal risk and compliance costs for us and the third parties with whom we work.

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 General Data Protection Regulation, or UK GDPR, Australia's Privacy Act, Brazil's General Data Protection Law (Lei Geral de Proteção de Dados Pessoais, Law No. 13,709/2018), South Korea's Personal Information Protection Act (PIPA), Chile's new Personal Data Protection Law (Law No. 21.719), Argentina's Personal Data Protection Law (PDPL), Mexico's Federal Law on the Protection of Personal Data held by Private Parties, and China's Personal Information Protection Law impose strict requirements for processing personal data. In Canada, the Personal Information Protection and Electronic Documents Act and various related provincial laws, as well as Canada's Anti-Spam Legislation, may apply to our operations.

For example, under the General Data Protection Regulation, or GDPR, companies may face temporary or definitive bans on data processing and other corrective actions; fines of up to 20 million Euros under the EU GDPR, and 17.5 million pounds sterling under the UK GDPR or, in each case, 4% of annual global revenue, whichever is greater; or 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.

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 United Kingdom 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 laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and the United Kingdom to the United States in compliance with law, such as the EEA's standard contractual clauses, the United Kingdom's International Data Transfer Agreement / Addendum and the European Union-U.S. Data Privacy Framework and the United Kingdom extension thereto (which allows for transfers to relevant U.S.-based organizations who self-certify compliance and participate in the Framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. If there is no lawful manner for us to transfer personal data from the EEA, the United Kingdom or other jurisdictions to the United States or if the requirements for a legally compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions (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. Additionally, companies that transfer personal data out of the EEA and the United Kingdom to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants and activities groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers of personal data out of Europe for allegedly violating the GDPR's cross-border data transfer limitations.

Additionally, the U.S. Department of Justice issued a rule entitled Preventing Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern or Covered Persons, which places additional restrictions on certain data transactions occurring on or after the effective date of the rule involving countries of concern (e.g., China, Russia, Iran) and covered persons (i.e., individuals and entities who are designated as such by the U.S. Attorney General or considered "foreign persons" and are majority owned by, organized under the laws of, a primary resident in, or a contractor of, a covered person or country of concern, as applicable) that may impact certain business and management activities, such as licensing and partnership engagements, vendor engagements, employment of or access to data by certain individuals, and investor agreements. Violations of the rule could lead to significant civil and criminal fines and penalties. Although the U.S. Department of Justice has issued compliance guidance and responded to frequently asked questions, there is currently no enforcement or case law to provide additional guidance on how the rule will be interpreted by the U.S. Department of Justice, and there is a risk that our interpretation of its applicability, scope and requirements could be incorrect, incomplete, or misapplied. The rule applies regardless of whether data is anonymized, key-coded, pseudonymized, de-identified or encrypted, which presents particular challenges for companies like ours and may impact our ability to transfer or provide access to data in connection with certain transactions or agreements.

We use or plan to use artificial intelligence, or AI, including generative AI, and machine learning, or ML, technologies in the development of our current or future product candidates (collectively, "AI/ML" technologies). For example, we use an internally developed algorithm for drug discovery purposes and to identify drug targets. The development and use of AI/ML present various privacy and security risks that may impact our business. AI/ML are subject to privacy and data security laws, as well as increasing regulation and scrutiny. Several jurisdictions around the globe, including Europe and certain U.S. states, have proposed enacted, or are considering laws governing the development and use of AI/ML, such as the EU's AI Act and Colorado's AI Act. We expect other jurisdictions will adopt similar laws. Additionally, certain privacy laws extend rights to consumers (such as the right to delete certain personal data) and regulate automated decision making, which may be incompatible with our use of AI/ML. These obligations may make it harder for us to conduct our business using AI/ML, lead to regulatory fines or penalties, require us to change our business practices, retrain our AI/ML, or prevent or limit our use of AI/ML. For example, the Federal Trade Commission has required other companies to turn over (or disgorge) valuable insights or trainings generated through the use of AI/ML where they allege the company has violated privacy and consumer protection laws. If we cannot use AI/ML or that use is restricted, our business may be less efficient, or we may be at a competitive disadvantage. Our employees and personnel also use AI and/or automated decision-making technologies to perform their work, and the disclosure and use of personal data in AI technologies is subject to various privacy laws and other privacy obligations. Governments have passed and are likely to pass additional laws regulating AI and/or automated decision-making technologies. Our use of this technology could result in additional compliance

costs, regulatory investigations and actions, and lawsuits. If we are unable to use generative AI and/or automated decision-making technologies, it could make our business less efficient and result in competitive disadvantages.

In addition to data privacy and security laws, we are and may in the future 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 publish privacy policies, marketing materials and other statements regarding data privacy and security. Regulators in the United States 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.

The requirements of such obligations, their application, and interpretation (and consumers' data privacy expectations) are quickly changing, becoming increasingly stringent, and creating uncertainty. Additionally, these obligations may be 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 may fail 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 government enforcement actions (e.g., investigations, fines, penalties, audits, inspections and similar); litigation (including class-action claims) and mass arbitration demands; additional reporting requirements and/or oversight; bans on processing personal data; orders to destroy or not use personal data; and imprisonment of company officials.

In particular, plaintiffs have become increasingly more active in bringing privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations. Any of these events could have a material adverse effect on our reputation, business or financial condition, including our inability to process personal data or to operate in certain jurisdictions; our limited ability to develop or commercialize our products; our expenditure of time and resources to defend any claim or inquiry; adverse publicity we may encounter; or by requiring substantial changes that may be required to our business model or operations.

We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws, and anti-money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We can face criminal liability and other serious consequences for violations, which can harm our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, the U.S. Foreign Corrupt Practices Act of 1977, as amended, or FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, and other collaborators from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties to sell our products outside the United States, to conduct clinical trials, and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors and other collaborators, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and

penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences.

A Fast Track designation from the FDA, even if granted for any of our product candidates, may not lead to a faster development or regulatory review or approval process, and does not increase the likelihood that our product candidates will receive regulatory approval.

The FDA has granted Fast Track designation to ML-007C-MA for the treatment of hallucinations and delusions associated with ADP. We intend to seek such designation for some or all of our additional product candidates. Drugs are eligible for Fast Track designation if they are intended, alone or in combination with one or more drugs 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 product development and, once an NDA is submitted, the application may be eligible for priority review. An NDA submitted 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.

The FDA has broad discretion whether or not to grant this designation. Even if we believe a particular product candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Even if we do receive Fast Track designation for any of our product candidates, such product candidates may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may also withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program. Furthermore, such a designation does not increase the likelihood that ML-007C-MA or any other product candidate that may be granted Fast Track designation will receive regulatory approval in the United States. Many product candidates that have received Fast Track designation have ultimately failed to obtain regulatory approval.

Risks Related to Our Reliance on Third Parties

We rely, and expect to continue to rely, on third parties, including independent clinical investigators, contracted laboratories and CROs, to conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties, comply with applicable regulatory requirements or meet expected deadlines, our development programs and our ability to seek or obtain regulatory approval for or commercialize our product candidates may be delayed and our business could be substantially harmed.

We have relied upon and plan to continue to rely upon third parties, including independent clinical investigators, contracted laboratories and third-party CROs, to conduct our preclinical studies and clinical trials in accordance with applicable regulatory requirements and to monitor and manage data for our ongoing preclinical and clinical programs. We rely on these parties for execution of our preclinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies and trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards and our reliance on these third parties does not relieve us of our regulatory responsibilities. We and our third-party contractors and CROs are required to comply with Good Laboratory Practice, or GLP, regulations as applicable, and GCP regulations, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for all of our products in clinical development. Regulatory authorities enforce these GLP and GCP regulations through periodic inspections of laboratories conducting GLP studies, trial sponsors, principal investigators and trial sites. If we, our investigators or any of our CROs or contracted laboratories fail to comply with applicable GLP and GCP regulations, the clinical data generated in our clinical trials may be deemed unreliable, we may be required to add more clinical trial sites or enroll additional participants and the FDA or comparable foreign regulatory authorities may require us to perform additional preclinical studies or clinical trials before approving our marketing applications. For example, certain companies developing drugs for the treatment of Alzheimer's disease and related conditions have recently reported enrolling irregularities and potential misconduct by certain of their clinical sites, including falsification of data and enrolling participants that may not have met inclusion and exclusion criteria. We cannot assure you that upon inspection by a given regulatory authority such

regulatory authority will determine that any of our preclinical studies or clinical trials comply with applicable GLP or GCP regulations. Further, these laboratories, investigators and CROs are not our employees, and we will not be able to control, other than by contract, the amount of resources, including time, that they devote to our product candidates and clinical trials. If independent laboratories, investigators or CROs fail to devote sufficient resources to the development of our product candidates, or if their performance is substandard, it may delay or compromise the prospects for approval and commercialization of any product candidates that we develop. In addition, the use of third-party service providers requires us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated.

Our CROs have the right to terminate their agreements with us in the event of an uncured material breach. In addition, some of our CROs have an ability to terminate their respective agreements with us if we make a general assignment for the benefit of our creditors or if we are liquidated.

If any of our relationships with these third-party laboratories, CROs or clinical investigators terminate, we may not be able to enter into arrangements with alternative laboratories, CROs or investigators or to do so in a timely manner or on commercially reasonable terms. If laboratories, CROs or clinical investigators do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our preclinical or clinical protocols, regulatory requirements or for other reasons, our preclinical or clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

Switching or adding additional laboratories or CROs or investigators involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new laboratory or CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Although we carefully manage our relationships with our contracted laboratories and CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition, results of operations and prospects.

In addition, clinical investigators may 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 preclinical study or clinical trial, the integrity of the data generated at the applicable preclinical study or clinical trial site may be questioned and the utility of the preclinical study or clinical trial itself may be jeopardized, which could result in the delay or rejection by the FDA. Any such delay or rejection could prevent us from commercializing our clinical-stage product candidate or any future product candidates.

We rely on third parties to supply and manufacture our product candidates, and we expect to continue to rely on third parties to manufacture our products, if approved. The development of such product candidates and the commercialization of any products, if approved, could be stopped, delayed or made less profitable if any such third party fails to provide us with sufficient quantities of product candidates or products or fails to do so at acceptable quality levels or prices or fails to maintain or achieve satisfactory regulatory compliance. Furthermore, our reliance on third parties, such as manufacturers, may subject us to risks relating to manufacturing scale-up, which may cause us to undertake substantial obligations, including financial obligations.

We do not currently have the infrastructure or capability internally to manufacture all our product candidates for use in the conduct of our preclinical studies and clinical trials or, if our products are approved, for commercial supply. We rely on, and expect to continue to rely on, contract manufacturing organizations, or CMOs. Any replacement of our CMOs could require significant effort and expertise because there may be a limited number of qualified CMOs. For example, we currently rely on a limited number of single-source suppliers for manufacturing components of ML-007C-MA. Reliance on third-party providers may expose us to more risk than if we were to manufacture our product candidates ourselves. We are dependent on our CMOs for the manufacture of our product candidates in accordance with relevant regulations, such as cGMP regulations, which require, among other things, quality control, quality assurance and the maintenance of records and documentation. Moreover, many of the third

parties with whom we contract may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting product development activities that could harm our competitive position.

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

Our third-party manufacturers and other vendors may be subject to damage or interruption from, among other things, fire, natural or man-made disaster, war, disease outbreaks or public health pandemics, power loss, telecommunications failure, unauthorized entry, computer viruses, denial-of-service attacks, acts of terrorism, human error, vandalism or sabotage, financial insolvency, bankruptcy and similar events.

If we were to experience an unexpected loss of supply of or if any supplier were unable to meet our demand for any of our product candidates, we could experience delays in our research or ongoing and planned clinical trials or commercialization. We could be unable to find alternative suppliers of acceptable quality, and with the appropriate volumes, who could meet our timelines at an acceptable cost. Moreover, our suppliers are often subject to strict manufacturing requirements and rigorous testing requirements, which could limit or delay production. The long transition periods necessary to switch manufacturers and suppliers, if necessary, could significantly delay our preclinical studies, our clinical trials and the commercialization of our products, if approved, which could materially and adversely affect our business, financial condition, results of operation and prospects. In complying with the applicable manufacturing regulations of the FDA and comparable foreign regulatory authorities, we and our third-party suppliers must spend significant time, money and effort in the areas of design and development, testing, production, record-keeping and quality control to assure that the products meet applicable specifications and other regulatory requirements. The failure to comply with these requirements could result in an enforcement action against us, including the seizure of products and shutting down of production. We and any of these third-party suppliers may also be subject to audits by the FDA and comparable foreign regulatory authorities. If any of our third-party suppliers fails to comply with cGMP regulations or other applicable manufacturing regulations, our ability to develop and commercialize the products could suffer significant interruptions. We face risks inherent in relying on CMOs, as any disruption, such as a fire, natural hazards, vandalism or an outbreak of contagious disease affecting the CMO or any supplier of the CMO could significantly interrupt our manufacturing capability. In case of a disruption, we will have to establish alternative manufacturing sources. This would require substantial capital on our part, which we may not be able to obtain on commercially acceptable terms or at all. Additionally, we would likely experience significant manufacturing delays as the CMO builds or locates replacement facilities and seeks and obtains necessary regulatory approvals. If this occurs, we will be unable to satisfy manufacturing needs on a timely basis, if at all.

In addition, we currently rely on foreign CMOs for manufacturing and development activities and will likely continue to rely on foreign CMOs in the future. Foreign CMOs may be subject to U.S. legislation, sanctions, trade restrictions and other foreign regulatory requirements which could increase the cost or reduce the supply of material available to us, delay the procurement or supply of such material or have an adverse effect on our ability to secure significant commitments from governments to purchase our potential therapies.

For example, the BIOSECURE Act, which was recently enacted as part of the fiscal year 2026 National Defense Authorization Act and signed by the President on December 18, 2025, prohibits U.S. federal agencies from entering into or renewing a contract with any company that uses biotechnology equipment or services produced or provided by a "biotechnology company of concern" in the performance of that contract, which may impact one of our CDMOs. It also prohibits loans or grant funding from U.S. federal agencies to entities that use any biotechnology equipment or services produced or provided by a "biotechnology company of concern" in the performance of the government grant or loan. This legislation could have the downstream effect of restricting the ability of pharmaceutical companies that enter into contracts with or receive funding from U.S. federal agencies from purchasing services or equipment from certain Chinese biotechnology companies, including those that are specifically named in the proposed BIOSECURE Act, as well as supply chain disruptions or delays. In addition to the BIOSECURE Act, any additional executive action, legislative action or potential sanctions with China could materially impact our work. U.S. executive agencies have the ability to designate entities and individuals on various governmental prohibited and restricted parties lists. Depending on the designation, potential consequences can range from a comprehensive prohibition on all transactions or dealings with designated parties or a limited prohibition on certain types of activities, such as exports and financing activities, with designated parties.

Furthermore, as we continue to grow and advance our product candidates through preclinical and clinical trials, we will need to scale our operations accordingly. For example, as we conduct clinical trials of our product candidates, we need to manufacture them in large quantities. We, or any manufacturing partners, may be unable to successfully increase the manufacturing capacity for any of our product candidates in a timely or cost-effective manner, or at all. In addition, quality issues may arise during scale-up activities. If we, or any manufacturing partners, are unable to successfully scale up the manufacture of our product candidates in sufficient quality and quantity, the development, testing, and clinical trials of that product candidate may be delayed or infeasible, and regulatory approval or commercial launch of any resulting product may be delayed or not obtained, which could materially and adversely affect our business, financial condition, results of operations and prospects.

Future partnerships may be important to our business. If we are unable to enter into new partnerships, or if these partnerships are not successful, our business could be adversely affected.

We have limited capabilities for product development and do not yet have any capability for commercialization. Accordingly, we may enter into future partnerships with other companies to provide us with additional product candidates and funding for our programs or to help commercialize our products, if approved. If we are unable to successfully develop and commercialize our own products and are required to pursue partnerships, we may fail to enter into or maintain such partnerships on reasonable terms or at all, our ability to develop our research programs and product candidates could be delayed and our costs of development and commercialization could increase. In addition, we may find that our programs require the use of intellectual property rights held by third parties, and the growth of our business may depend in part on our ability to acquire or in-license these intellectual property rights.

We may not be able to negotiate partnerships on a timely basis, on acceptable terms, or at all. Our ability to reach a definitive agreement for a partnership will depend, among other things, upon an assessment of the partner's resources and expertise, the terms and conditions of the proposed partnership and the proposed partner's evaluation of a number of factors. These factors may include the design or results of preclinical studies or clinical trials, the likelihood of regulatory approval, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of any uncertainty with respect to our ownership of technology (which can exist if there is a challenge to such ownership regardless of the merits of the challenge) and industry and market conditions generally. The partner may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a partnership could be more attractive than the one with us.

Risks Related to Employee Matters and Our Operations

Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.

We are highly dependent on the management, clinical, research and development, manufacturing, financial and business development expertise of our executive officers, particularly Christopher A. Kroeger, M.D., our Chief

Executive Officer and Founder, and Erin Foff, M.D., Ph.D., our Chief Medical Officer. Each of our executive officers may currently terminate their employment with us at any time. We do not currently maintain "key person" insurance for any of our executives or employees.

Recruiting and retaining qualified scientific and clinical personnel and, if we progress the development of our product pipeline for commercialization, manufacturing and sales and marketing personnel, will also be critical to our success. The loss of the services of our executive officers or other key personnel, including any of our scientific founders, could impede the achievement of our development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited, and our business, financial condition, results of operations and prospects could be materially and adversely affected.

We expect to expand our clinical development, manufacturing and regulatory capabilities and potentially implement sales, marketing and distribution capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

As our development progresses, we expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of clinical product development, regulatory affairs and, if any of our product candidates receives marketing approval, sales, marketing and distribution. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. Our choice to focus on multiple CNS indications may negatively affect our ability to adequately develop the specialized capability and expertise necessary for operations. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

Our employees, independent contractors, consultants, collaborators, principal investigators, CROs, suppliers and vendors may be improperly classified or may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.

We endeavor to properly classify our employees as exempt or non-exempt with respect to wage and hour laws, including for purposes of minimum wage, overtime and applicable meal and rest periods, and we monitor and evaluate such classifications. Although there are no current, pending or threatened claims or investigations against us asserting that any employees have been incorrectly classified as exempt, the possibility nevertheless exists that certain job roles could be deemed to have been incorrectly classified as exempt. In addition, we endeavor to classify our workforce properly, and we monitor and evaluate such classifications. Although there are no current, pending or threatened claims or investigations against us asserting that any independent contractors have been incorrectly classified, the possibility nevertheless exists that certain contractors could be deemed to be employees.

We are exposed to the risk that our employees, independent contractors, consultants, collaborators, principal investigators, CROs, suppliers and vendors may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct that violates FDA regulations, including those laws requiring the reporting of true, complete and accurate information to the FDA, manufacturing standards, federal and state healthcare laws and regulations, and laws that require the true, complete and accurate reporting of financial information or data. 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. Misconduct by these parties could also involve the improper use of individually identifiable information, including, without limitation, information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter 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 be in compliance 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 significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, including, without limitation, damages, fines, disgorgement, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws and the curtailment or restructuring of our operations.

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 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 our business, we and the third parties with whom we work process sensitive data, and, as a result, we and third parties with whom we work face a variety of evolving threats that can 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 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 third parties 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 third parties with whom we work are subject to a variety of evolving threats, including 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, human or technological error, ransomware attacks, supply chain attacks, software bugs or other vulnerabilities in commercial software that is integrated into our or our service providers' information technology systems, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, attacks enhanced or facilitated by AI (including tools that that circumvent security controls, evade detection and remove forensic evidence), telecommunications failures, earthquakes, fires, floods, and other similar threats. Such threats are expected to accelerate on a global basis in frequency and magnitude as threat actors are becoming increasingly sophisticated in using techniques and tools.

In particular, severe ransomware attacks are becoming increasingly prevalent and can lead to significant interruptions in our operations or our 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 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 to gain access to other parts of our environment, or leverage a compromise of our 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 our employees utilize network connections, computer and devices outside our premises or network, including working at home, while in transit and in public locations. Additionally, 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 third parties and their technologies to operate critical business systems to process sensitive data in a variety of contexts, including, without limitation, CROs, cybersecurity service providers, employee email and other functions. We also rely on third parties to provide other products, services, parts or otherwise to operate our business. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If 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 the third parties with whom we work 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 their supply chains 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 take steps designed to detect, mitigate and remediate vulnerabilities in our information systems (such as our hardware and/or software, including that of third parties with whom we work). However, we may not 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.

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

We may need to expend additional resources or may have to modify our business activities (including our clinical trial activities) to try to protect against security incidents. Additionally, certain data privacy and security obligations 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, customers, regulators and investors, of security incidents, or to take other actions, such as providing credit monitoring and identity theft protection services. Such disclosures and related action can be costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences.

Our use of AI/ML presents certain information security risks. For example, any sensitive data that we input into an AI/ML platform could be leaked or disclosed to others, including if sensitive data is used to train third-party AI/ML. Where an AI/ML model ingests sensitive data and makes connections using such data, those technologies may reveal other sensitive data generated by the model. AI/ML models may create flawed, incomplete, or inaccurate outputs, some of which may appear correct. This may happen if the inputs that the model relied on were inaccurate,

incomplete or flawed (including if a bad actor "poisons" the AI/ML with bad inputs or logic), or if the logic of the AI/ML is flawed (a so-called "hallucination").

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 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, diversion of our capital resources, diversion of management attention, interruptions in our operations (including availability of data), financial loss, and other similar harms. Security incidents and attendant consequences may negatively impact our ability to grow and operate our business. Any or all of the foregoing could materially adversely affect our business, financial condition, results of operations and prospects.

Some of our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages or claims related to our data privacy and security obligations.

We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

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 reveal competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations, and those of our CROs, CMOs and other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We rely on third-party manufacturers to produce our product candidates. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain sufficient intellectual property protection for our current or future product candidates or if the scope of the intellectual property protection we currently have or obtain in the future is not sufficiently broad, our competitors could develop and commercialize product candidates similar or identical to ours, and our ability to successfully commercialize our current or future product candidates may be impaired.

Our success depends in large part on our ability to obtain, maintain, defend and enforce our intellectual property, particularly patents, in the United States and other countries with respect to our product candidates and technology. We seek to protect our proprietary position by filing patent applications in the United States and abroad and in-licensing intellectual property related to our existing product candidates, our various proprietary technologies and any other product candidates or technologies that we may identify.

Obtaining and enforcing biopharmaceutical patents is costly, time consuming and complex, and we may not be able to file and prosecute all necessary or desirable patent applications, or maintain, enforce and license any patents that may issue from such patent applications, at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. We may not have the right to control the preparation, filing and prosecution of patent applications or to maintain the rights to patents licensed from third parties. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

The patent position of biopharmaceutical companies generally is highly uncertain, involves complex legal, technological and factual questions and has in recent years been the subject of significant litigation. The standards that the U.S. Patent and Trademark Office, or USPTO, and its foreign counterparts use to grant patents are not always applied predictably or uniformly. 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. There is no assurance that all potentially relevant prior art relating to our patents and patent applications has been found, which can prevent a patent from issuing from a pending application or later invalidate or narrow the scope of an issued patent. For example, 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. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. In some instances, we submit patent applications directly with the USPTO as provisional patent applications. However, U.S. provisional patent applications are not eligible to become issued patents unless and until, among other things, we file a non-provisional patent application within 12 months of the provisional application filing date. With regard to such U.S. provisional patent applications, if we do not timely file any non-provisional patent applications, we may lose our priority date with respect to our provisional patent applications and any patent protection on the inventions disclosed in our provisional patent applications. Any pending and future patent applications that we own or in-license may not result in patents being issued that protect our product candidates or technology, in whole or in part, or that effectively prevent others from commercializing competitive product candidates. The coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative product candidates in a non-infringing manner.

In addition, the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges 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 or identical product candidates to ours or limit the duration of the patent protection of our product candidates. 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. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing drugs similar or identical to ours.

Furthermore, our owned and in-licensed intellectual property rights may be subject to a reservation of rights by one or more third parties. Certain intellectual property related to the ML-007C-MA product candidate that is expected to expire between 2031 and 2032 was developed using U.S. governmental funding. When new technologies are developed with government funding, the government generally obtains certain rights in any resulting patents, including a non-exclusive license authorizing the government to use the invention or to have others use the invention on its behalf. These rights 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. For example, the United States federal government retains such rights in inventions produced with its financial assistance under the Bayh-Dole Act. The government can exercise its march-in rights if it determines that action is necessary because we fail to achieve practical application of the government-funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations or to give preference to U.S. industry. Any exercise by the government of such rights or by any third party of its reserved rights could materially and adversely affect our competitive position, 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 our product candidates in all countries throughout the world would be prohibitively expensive. In addition, intellectual property rights in some countries outside the United States can be less extensive than those in the United States. Moreover, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the

United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. In addition, competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and may also export infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biopharmaceutical products, 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 generally. For example, in European Union countries, compulsory licensing laws compel patent owners to grant licenses to third parties. In addition, some countries limit the enforceability of patents against government agencies or government contractors. Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Similarly, if our trade secrets are disclosed in a foreign jurisdiction, competitors worldwide could have access to our proprietary information and we may be without satisfactory recourse. Such disclosure could have a material adverse effect on our business. Moreover, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws, which could limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

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 current or future licensors and the maintenance, enforcement or defense of our issued patents or those of any current or future licensors. For example, the United States and foreign government actions related to Russia's invasion of Ukraine may limit or prevent filing, prosecution and maintenance of patent applications in Russia. Government actions may also prevent maintenance of issued patents in Russia. These actions could result in abandonment or lapse of our patents or patent applications, resulting in partial or complete loss of patent rights in Russia. If such an event were to occur, it could have a material adverse effect on our business. In addition, a decree was adopted by the Russian government in March 2022 allowing Russian companies and individuals to exploit inventions owned by patentees from the United States without consent or compensation. Consequently, we would not be able to prevent third parties from practicing our inventions in Russia or from selling or importing products made using our inventions in and into Russia. Accordingly, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be materially and adversely affected.

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

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. Assuming that other requirements for patentability were met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to a patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy Smith America Invents Act, or the America Invents Act, enacted in September 2011, the United States transitioned to a first-inventor-to-file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. A third party that files a patent application in the USPTO before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This new regime will require us to be cognizant of the time from invention to filing of a patent application and be diligent in filing patent applications, but circumstances could prevent us from promptly filing patent applications on our inventions. Since patent applications in the United States and most other countries are confidential for a period after

filing or until issuance, we cannot be certain that we or our licensors were the first to either (i) file any patent application related to our product candidates or (ii) invent any of the inventions claimed in our or our licensor's patents or patent applications.

The America Invents Act also includes a number of significant changes that affect the way patent applications filed after March 2013 are prosecuted and also may affect patent litigation. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO-administered post-grant proceedings, including post-grant review, inter partes review and derivation proceedings. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Therefore, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our owned or in-licensed patent applications and the enforcement or defense of our owned or in-licensed issued patents, all of which could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

In addition, the patent positions of companies in the development and commercialization of biopharmaceuticals are particularly uncertain. For example, U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. For instance, in *Amgen Inc. v. Sanofi*, the U.S. Supreme Court held that claims with functional language may pose high hurdles in fulfilling the enablement requirement. This combination of events has created uncertainty with respect to the validity and enforceability of patents, once obtained. Depending on future actions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property in the future. For example, recent decisions, including by the U.S. Court of Appeals for the Federal Circuit, raise questions regarding the award of patent term adjustment, or PTA, for patents in families where related patents have issued without PTA. Thus, it cannot be said with certainty how PTA will/will not be viewed in the future and whether patent expiration dates may be impacted.

Further, the new European unitary patent system took effect on June 1, 2023, under which all European patents, including those granted before the introduction of the system, now by default fall automatically under the jurisdiction of the Unitary Patent Court, or UPC, unless otherwise opted out. Under the unitary patent system, European applications will have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the UPC. Patents granted before the implementation of the UPC will have the option of opting out of the jurisdiction of the UPC during the first seven years of the court's existence and remaining as national patents in the UPC countries. Patents that remain under the jurisdiction of the UPC will be potentially vulnerable to a single UPC-based revocation challenge that, if successful, could invalidate the patent in all countries who are signatories to the UPC. As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation. We cannot predict with certainty the long-term effects of any potential changes.

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

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional or international patent application filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products. 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. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

If we are not able to obtain patent term extension in the United States under the Hatch-Waxman Amendments and in foreign countries under similar legislation, thereby potentially extending the marketing exclusivity term of our product candidates, our business may be materially harmed.

Depending upon the timing, duration and specifics of FDA marketing approval of our product candidates, one of the U.S. patents covering each of such product candidates or the use thereof may be eligible for up to five years of patent term extension under the Hatch-Waxman Amendments. The Hatch-Waxman Amendments allow a maximum of one patent to be extended per FDA-approved product as compensation for the 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, and only those claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. Patent term extension also may be available in certain foreign countries upon regulatory approval of our product candidates, such as the Supplementary Protection Certificates in Europe. In particular, a maximum of five-and-a-half years of supplementary protection can be achieved in Europe for an active ingredient or combinations of active ingredients of a medicinal product protected by a basic patent, if a valid marketing authorization exists (which must be the first authorization to place the product on the market as a medicinal product) and if the product has not already been the subject of supplementary protection.

Nevertheless, we may not be granted patent term extension either in the United States or in any foreign country because of, for example, any failure by us to exercise due diligence during the testing phase or regulatory review process, apply within applicable deadlines, apply prior to expiration of relevant patents or to otherwise satisfy applicable requirements. Moreover, the term of extension, as well as the scope of patent protection during any such extension, afforded by the governmental authority could be less than we request.

If we are unable to obtain patent term extension or restoration, or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our product may be shortened and our competitors may obtain approval of competing products following our patent expiration and may take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data to launch their product earlier than might otherwise be the case, and our revenue could be reduced, possibly materially, which would have a material adverse effect on our business, financial condition, results of operations and prospects.

Also, there are detailed rules and requirements regarding the patents that may be submitted to the FDA for listing in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, or the Orange Book. We may be unable to obtain patents covering our product candidates that contain one or more claims that satisfy the requirements for listing in the Orange Book. Even if we submit a patent for listing in the Orange Book, the FDA may decline to list the patent or a manufacturer of generic drugs may challenge the listing. If or when one of our product candidates is approved and a patent covering that product candidate is not listed in the Orange Book, a manufacturer of generic drugs would not have to provide advance notice to us of any Abbreviated New Drug Application filed with the FDA to obtain permission to sell a generic version of such product candidate.

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:

- we or future collaborators might not have been the first to make the inventions covered by the issued patent or pending patent application that we license or may own in the future;
- 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, manufacture and commercialize technologies or products that are similar to, or are alternatives or duplicates of any of our technologies or products without infringing, misappropriating or otherwise violating our intellectual property rights;
- it is possible that our pending patent applications or those that we may own in the future will not lead to issued patents;

- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop, manufacture and commercialize competitive products or product candidates for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may harm our business; and
- we may choose not to seek patent protection for some of our proprietary technology to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such trade secrets or know-how.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of our owned and licensed patents and/or applications. We have systems in place to remind us to pay these fees, and we employ outside firms and rely on outside counsel to pay these fees due to the USPTO and non-U.S. patent agencies. However, we cannot guarantee that any current or future licensors have or will have similar systems and procedures in place to pay such fees. In addition, the USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and 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. However, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors might be able to enter the market and this circumstance would have a material adverse effect on our business, financial condition, results of operations and prospects.

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

Our current or future registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or descriptive, cancelled, or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using those names, which we need to build name recognition among potential collaborators or customers in our markets of interest. At times, competitors 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 trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. If we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

During trademark registration proceedings, we may receive rejections of our applications by the USPTO or in other foreign jurisdictions. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel

registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively, and our business may be adversely affected. We may license our trademarks and trade names to third parties, such as distributors. Although these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and tradenames by any licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names. Our efforts to enforce or protect our proprietary rights related to trademarks, trade names, trade secrets, domain names, copyrights or other intellectual property may be ineffective, could result in substantial costs and diversion of resources and could materially and adversely affect our competitive position, business, financial condition, results of operations and prospects.

Moreover, any name we have proposed to use with any of our product candidates in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. Similar requirements exist in Europe. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA (or an equivalent administrative body in a foreign jurisdiction) objects to any of our proposed proprietary product names, 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 become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time consuming and unsuccessful, and our issued patents covering our product candidates could be found invalid or unenforceable if challenged in courts or patent offices.

Competitors or other third parties may infringe our patents, trademarks, copyrights or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming and divert the time and attention of our management and 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. If we were to initiate legal proceedings against a third party to enforce a patent covering one or more of our product candidates, the defendant could allege that we infringe their patents, assert counterclaims that the patent covering our product candidate is invalid and/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 novelty, nonobviousness, written description or enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. The outcome following legal assertions of invalidity and unenforceability is unpredictable. In any patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention, or decide that the other party's use of our patented technology falls under the safe harbor to patent infringement under 35 U.S.C. § 271(e)(1). An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitors and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the

price of our common shares. Moreover, we may not have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings.

Further, interference or derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications. An unfavorable outcome could require us to cease using the related technology or attempt to obtain a license to use the related technology from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms or at all, or if a non-exclusive license is offered and our competitors gain access to the same technology. Our defense of litigation or interference or derivation proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue clinical trials, continue research programs, license necessary technology from third parties or enter into development partnerships that would help us bring product candidates to market.

Third parties may claim that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain and may prevent or delay our development and commercialization efforts.

Our commercial success depends in part on our ability to develop, manufacture, market and sell any product candidates that we may develop without infringing, misappropriating or otherwise violating the intellectual property and proprietary rights of third parties. However, our research, development and commercialization activities may be subject to claims that we infringe or otherwise violate patents or other intellectual property rights owned or controlled by third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biopharmaceutical industry, including patent infringement lawsuits, interferences, oppositions and inter partes reexamination proceedings before the USPTO and corresponding foreign patent offices. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are pursuing development candidates. 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 or obtain patents that could prevent, limit or otherwise interfere with our ability to make, use and sell, if approved, our product candidates. The biopharmaceutical 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 product candidates, products or methods 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. For example, in the United States, proving invalidity in court requires a showing of clear and convincing evidence to overcome the presumption of validity that applies to issued patents, and a court of competent jurisdiction may not invalidate the claims of any such U.S. patent. In addition, many companies in the biopharmaceutical industry have employed intellectual property litigation as a means to gain an advantage over their competitors. As the biopharmaceutical industry expands and more patents are issued, and as we gain greater visibility and market exposure as a public company, the risk increases that our existing product candidates and any other product candidates that we may identify may be subject to claims of infringement of the patent rights of third parties.

There may be other third-party patents or patent applications with claims to composition of matter, materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our existing or future product candidates. Further, we may not be aware of patents that have already been issued and that a third party might assert are infringed by our current or future product candidates, including claims to compositions, formulations, methods of manufacture or methods of use or treatment that cover our product candidates. It is also possible that patents owned by third parties of which we are aware, but which we do not believe are relevant to our product candidates and other proprietary technologies we may develop, could be found to be infringed by our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were determined to cover the manufacturing process of our product candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block

our ability to commercialize such product candidate unless we obtained a license under the applicable patents or until such patents expire.

Similarly, if any third-party patents were found to cover aspects of our formulations, processes for manufacture or methods of use, the holders of any such patents may be able to block our ability to develop and commercialize the applicable product candidate unless we obtained a license or until such patent expires. In either case, such a license may not be available on commercially reasonable terms or at all, or it may be non-exclusive, which could result in our competitors gaining access to the same intellectual property rights.

Parties making claims against us may be able to sustain the costs of complex patent litigation more effectively than we could because they have substantially greater resources. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, financial condition, results of operations and prospects.

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

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

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

Our agreements with employees and contractors and our personnel policies provide that any inventions conceived by an individual in the course of rendering services to us is our exclusive property. Although our policy is to have all such individuals complete these agreements assigning such intellectual property to us, we may not obtain these agreements in all circumstances, the assignment of intellectual property rights may not be self-executing and individuals with whom we have entered into these agreements may not comply with their terms. The assignment of intellectual property may not be automatic upon the creation of an invention and despite such agreement, such inventions may become assigned to third parties. In the event of unauthorized use or disclosure of our trade secrets or proprietary information, these agreements, even if obtained, may not provide meaningful protection.

We or our current or future licensors may be subject to claims that former employees, collaborators or other third parties have an interest in our owned or in-licensed patents, trade secrets or other intellectual property as an inventor or co-inventor. For example, we or our licensors may have inventorship disputes arising from conflicting obligations of employees, consultants or others who are involved in developing our product candidates. The failure to name the proper inventors on a patent application can result in the patents issuing thereon being unenforceable. Litigation may be necessary to defend against these and other claims challenging inventorship of our or our licensors' ownership of our owned or in-licensed patents, trade secrets or other intellectual property. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. If we or our licensors 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 intellectual property that is important to our product candidates. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Our current or future licensors may have relied on third-party consultants or collaborators or on funds from third parties, such as the U.S. government, such that our licensors are not the sole and exclusive owners of the patents we in-licensed. If other third parties have ownership rights or other rights to our in-licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products and technology.

Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

If we are unable to protect the confidentiality of our trade secrets, the value of our technology could be materially adversely affected and our business would be harmed.

We consider proprietary trade secrets, confidential know-how and unpatented know-how to be important to our business. We seek to protect our confidential proprietary information, in part, by entering into confidentiality agreements and invention assignment agreements with parties who have access to them, including our employees, consultants, scientific advisors, contractors, CROs, contract manufacturers, collaborators and other third parties, that are designed to protect our proprietary information. However, we cannot be certain that such agreements have been entered into with all relevant parties that may have or have had access to our trade secrets or proprietary technology, and 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 and other confidential proprietary technology or independently develop substantially equivalent information and techniques. For example, any of these parties may breach the agreements and disclose our proprietary information, including trade secrets, and we may not be able to obtain adequate remedies for such breaches. We also seek to preserve the integrity and confidentiality of our confidential proprietary information by maintaining physical security of our premises and physical and electronic security of our information technology systems, but it is possible that these security measures could be breached. Monitoring unauthorized uses and disclosures of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be effective.

Unauthorized parties may also attempt to copy or reverse engineer certain aspects of our products that we consider proprietary. We may not be able to obtain adequate remedies in the event of such unauthorized use. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets, and we may need to share our trade secrets or 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, foreign actors and those affiliated with or controlled by state actors. Over time, trade secrets may also be disseminated within the industry through independent development, the publication of journal articles and the movement of personnel from company to company or academic institutions to industry scientific positions. Although our agreements with third parties typically restrict the ability of our advisors, employees, collaborators, licensors, suppliers, third-party contractors and consultants to publish data potentially relating to our trade secrets and proprietary information, our agreements may contain certain limited publication rights. In addition, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position. Despite employing the contractual and other security precautions described above, the need to share trade secrets increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others or are disclosed or used in violation of these agreements. If any of these events occurs or if we otherwise lose protection for our trade secrets, the value of such information may be greatly reduced and our competitive position, business, financial condition, results of operations and prospects would be materially and adversely affected.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed alleged trade secrets or other confidential information of their current or former employers or other third parties.

As is common in the biopharmaceutical industry, we employ individuals who were previously employed at universities or other biotechnology or pharmaceutical companies. Although we try to ensure that our employees, consultants and independent contractors do not use the intellectual property, proprietary information, know-how or trade secrets of others in their work for us, we may be subject to claims that we or our employees, consultants or

independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer or other third parties. We may also become subject to claims that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, a court could prohibit us from using technologies or features that are essential to our product candidates, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. We may also lose valuable intellectual property rights or personnel, which could adversely impact 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. Moreover, any such litigation or the threat thereof may adversely affect our reputation, our ability to form strategic alliances or sublicense our rights to collaborators, engage with scientific advisors or hire employees or consultants, each of which would have an adverse effect on our business, financial condition, results of operations and prospects.

We may obtain rights to develop and commercialize product candidates that are subject in part to the terms and conditions of licenses granted to us by others. The terms of these licenses may be inadequate to protect our competitive position on product candidates. Further, if we fail to comply with our obligations in the agreements under which we in-license or acquire development or commercialization rights to product candidates, we could lose such rights that are important to our business.

We may in the future seek licenses from others to develop and commercialize product candidates or technologies. The licenses we may enter into may not provide adequate rights to use such intellectual property rights and proprietary technology in all relevant fields of use or in all territories in which we may wish to develop or commercialize technology and product candidates in the future. Licenses to additional third-party proprietary technology or intellectual property rights that may be required for our development programs may not be available in the future or may not be available on commercially reasonable terms. In that event, we may be required to expend significant time and resources to redesign our proprietary technology or product candidates or to develop or license replacement technology, which may not be feasible on a technical or commercial basis. If we are unable to do so, we may not be able to develop and commercialize technology and product candidates in fields of use and territories for which we are not granted rights pursuant to such licenses, which could materially and adversely affect our competitive position, business, financial condition, results of operations and prospects.

We may not have the right to control the preparation, filing, prosecution and enforcement of patent applications, or to maintain the patents, covering technology that we license from third parties. In addition, our licensors may require us to obtain consent from the licensor before we can enforce patent rights, and our licensor may withhold such consent or may not provide it on a timely basis. Therefore, we cannot be certain that our licensors or collaborators will prosecute, maintain, enforce and defend such intellectual property rights in a manner consistent with the best interests of our business, including by taking reasonable measures to protect the confidentiality of know-how and trade secrets or by paying all applicable prosecution and maintenance fees related to intellectual property registrations for any of our product candidates. We also cannot be certain that our licensors have drafted or prosecuted the patents and patent applications licensed to us in compliance with applicable laws and regulations, which may affect the validity and enforceability of such patents or any patents that may issue from such applications. This could cause us to lose rights in any applicable intellectual property that we in-license, and as a result our ability to develop and commercialize product candidates may be adversely affected, and we may be unable to prevent competitors from making, using and selling competing products.

Our rights to use any intellectual property that we may license in the future will be subject to the continuation of and our compliance with the terms of such a license agreement. Disputes may arise regarding intellectual property subject to a licensing agreement, including:

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

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

In addition, certain provisions in our license agreements may be susceptible to multiple interpretations. Any disagreements regarding contract interpretation that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we license prevents or impairs our ability to maintain our licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

In addition, our licensors may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to claims, regardless of their merit, that we are infringing or otherwise violating the licensor's rights. In addition, while we cannot currently determine the amount of the royalty obligations we would be required to pay on sales of future products if infringement or misappropriation were found, those amounts could be significant. The amount of our future royalty obligations will depend on the technology and intellectual property we use in products that we successfully develop and commercialize, if any. Therefore, even if we successfully develop and commercialize products, we may be unable to achieve or maintain profitability.

Risks Related to Ownership of our Common Stock and our Status as a Public Company

An active trading market for our common stock may not continue to be sustained.

An active trading market for our shares may not be sustained. You may not be able to sell your shares quickly or at the market price if trading in shares of our common stock is not active. As a result of these and other factors, you may be unable to resell your shares of our common stock at the time you wish to sell them, or at a price that you consider reasonable. The lack of an active market may also reduce the fair market value of your shares. Further, an inactive market also may impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic partnerships or acquire companies or products by using our shares of common stock as consideration.

The trading price of shares of our common stock may be volatile, and purchasers of our common stock could lose all of part of their investment.

The trading price of our common stock could be highly volatile and subject to wide fluctuations in response to various factors, some of which are beyond our control. The stock market in general and the market for biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their common stock at or above the price paid for the shares. In addition to the factors described in this "Risk Factors" section and elsewhere in this Annual Report on Form 10-K, the market price for our common stock may be influenced by many factors, including:

- the initiation, enrollment or results of our current or future clinical trials we may conduct or changes in the development status of our product candidates;
- any delay in our regulatory filings for our current or future product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including without limitation the FDA's issuance of a "refusal to file" letter or a request for additional information;
- adverse results from, delays in or termination of clinical trials;
- the reporting of unfavorable clinical or preclinical results;
- adverse regulatory decisions, including failure to receive regulatory approval of our product candidates;

- unanticipated serious safety concerns related to the use of our current or future product candidates;
- our inability to obtain adequate product supply for any approved product or inability to do so at acceptable prices;
- general conditions or trends in the biotechnology and other industries;
- the overall performance of the equity markets generally, including the stock market performance and volume fluctuations of comparable companies and, in particular, those that operate in the biopharmaceutical industry;
- publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- investors' general perception of our company and our business;
- our failure to meet the third-party estimates and projections of the investment community or those that we may otherwise provide to the public;
- changes in financial estimates published by us or by any equity research analysts who might cover our stock;
- the trading volume of our common stock;
- announcements by us or our competitors of entry into significant acquisitions, strategic partnerships or divestitures;
- introduction of new products or services offered by us or our competitors;
- announcements of investigations or regulatory scrutiny of our operations or lawsuits filed against us;
- our ability to effectively manage our growth;
- recruitment or departure of key personnel;
- ineffectiveness of our internal controls;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including patent or stockholder litigation or employee or independent contractor litigation;
- significant changes in the structure of healthcare payment systems, including with respect to coverage and adequate reimbursement for any approved drug;
- expiration of market standoff or lock-up agreements entered into in connection with our initial public offering; and
- other events or factors, many of which are beyond our control.

In addition, in the past, securities class action litigation often has been instituted against companies following periods of volatility in the market price of a company's securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources, which could materially and adversely affect our business, financial condition, results of operations and prospects.

If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business or our market, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that equity research analysts publish about us and our business. As a newly public company, we have limited research coverage by equity research analysts. Equity research analysts may elect not to provide research coverage of our common stock, and such lack of research coverage may materially and adversely affect the market price of our common stock. In the event we do have equity research analyst coverage, we will not have any control over the analysts or the content and opinions included in their reports. The price of our common stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research

analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which in turn could cause our stock price or trading volume to decline.

We could be subject to securities class action 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-listed and biotechnology 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, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs (including the cost to defend against and any potential adverse outcome resulting from any such proceeding), damage to our reputation and a diversion of management's attention and resources from other business concerns, which could harm our business, financial condition, results of operations and prospects.

Our executive officers, directors and principal stockholders, if they choose to act together, have the ability to significantly influence all matters submitted to stockholders for approval.

Our executive officers, directors and stockholders who own more than 5% of our outstanding common stock and their respective affiliates, including Catalyst4, Inc., in the aggregate, hold common stock representing a majority of our outstanding voting common stock. As a result, if these stockholders choose to act together, they would be able to control or significantly influence all matters submitted to our stockholders for approval, as well as our management and affairs. Additionally, the concentration of stock ownership may adversely affect the trading price of our common stock due to investors' perception that conflicts of interest may exist or arise.

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

We currently anticipate that we will retain future earnings for the research, development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any future debt or other financing arrangements may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. Any return to stockholders therefore will be limited to the appreciation in the price of our common stock.

A significant portion of our total outstanding shares is restricted from immediate resale but may be sold into the market in the near future. Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. The 16,962,500 shares of common stock that we sold in our initial public offering may be resold in the public market at any time, subject to volume limitations in the case of our affiliates. Substantially all of our shares that were outstanding prior to our initial public offering are subject to a 180-day lock-up period pursuant to the lock-up agreements executed in connection with our initial public offering. Substantially all of these shares will, however, be able to be resold after the expiration of the lock-up period, as well as pursuant to customary exceptions thereto or upon the waiver of the lock-up agreement by or on behalf of the underwriters of our initial public offering.

Both the 2025 Equity Incentive Plan and the 2025 Employee Stock Purchase Plan that we established in connection with our initial public offering provide for annual automatic increases in the shares reserved for issuance under the plans which could result in additional dilution to our stockholders. These shares can be freely sold in the public market upon issuance, subject to the vesting of the equity awards, other restrictions provided under the terms of the applicable plan or equity award, the 180-day lock-up period described above and volume limitations in the case of our affiliates.

We are an "emerging growth company" and a "smaller reporting company" and, as a result of the reduced disclosure and governance requirements applicable to emerging growth companies and smaller reporting companies, our common stock may be less attractive to investors.

We are an "emerging growth company" as defined in the JOBS Act, and we intend to take advantage of some of the exemptions from reporting requirements that are applicable to other public companies that are not emerging growth companies, including:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;
- an exemption from compliance with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended, in the assessment of our internal control over financial reporting;
- reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements and registration statements;
- exemptions from the requirements to hold non-binding advisory votes on executive compensation or golden parachute arrangements; and
- an exemption from compliance with the requirements of the PCAOB regarding the communication of critical audit matters in the auditor's report on financial statements.

We cannot predict if investors will find our common stock less attractive because we will 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. We plan to take advantage of these reporting exemptions until we are no longer an emerging growth company. We will remain an emerging growth company until the last day of our fiscal year following the fifth anniversary of the completion of our initial public offering or, if earlier, (i) the last day of the fiscal year in which we have total annual gross revenue of at least $1.235 billion, (ii) the date on which we are deemed to be a large accelerated filer, which means the market value of our common stock held by non-affiliates exceeds $700 million as of the prior June 30th (and we have been a public company for at least 12 months and have filed one annual report on Form 10-K) or (iii) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

In addition, we have elected to take advantage of the extended transition period to comply with new or revised accounting standards and to adopt certain of the reduced disclosure requirements available to emerging growth companies. As a result of the accounting standards election, we will not be subject to the same implementation timing for new or revised accounting standards as other public companies that are not emerging growth companies, which may make comparison of our financials to those of other public companies more difficult. As a result of these elections, the information that we provide in this Annual Report may be different than the information investors may receive from other public companies in which they hold equity interests. In addition, it is possible that some investors will find our common stock less attractive as a result of these elections, which may result in a less active trading market for our common stock and higher volatility in our share price.

We also are a "smaller reporting company," which allows us to take advantage of many of the same exemptions from disclosure requirements, including reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We will continue to be a smaller reporting company if either (i) the market value of our stock held by non-affiliates is less than $250 million or (ii) our annual revenue is less than $100 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700 million. 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.

We have broad discretion in the use of our cash, cash equivalents and investments and may invest or spend the proceeds in ways with which you do not agree and in ways that may not increase the value of your investment.

Our management has broad discretion over the use of our cash, cash equivalents and investments, and you will not have the opportunity to assess whether such proceeds are being used appropriately. Because of the number and variability of factors that determine our use of our existing cash, cash equivalents and investments, our ultimate use of proceeds may vary substantially from their currently intended use. Our management might not apply our existing cash, cash equivalents and investments in ways that ultimately increase the value of your investment. The failure by our management to apply these funds effectively could harm our business. We expect to use our existing cash, cash equivalents and investments to advance the clinical development of our current programs, to fund research and development activities for additional programs, and for working capital and other general corporate purposes. In addition, we may use a portion of our existing cash, cash equivalents and investments to pursue our strategy to in-license or develop additional product candidates. We may also invest in short- and long-term, investment-grade, interest-bearing securities. These investments may not yield a favorable return to our stockholders. If we do not invest our existing cash, cash equivalents and investments in ways that enhance stockholder value, we may fail to achieve expected financial results, which could cause our stock price to decline.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware and the federal district courts of the United States 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 provides 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 Delaware General Corporation Law, or DGCL, our amended and restated certificate of incorporation or our amended and restated bylaws;
- any claim or cause of action seeking to interpret, apply, enforce or determine the validity of our restated certificate or our amended and restated bylaws;
- any claim or cause of action as 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. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation further provides that the federal district courts of the United States 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, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions.

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

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

Provisions in our certificate of incorporation and our bylaws may discourage, delay or prevent a merger, acquisition or other change in control of our company that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, 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. Among other things, these provisions:

- establish a classified board of directors such that directors are elected at the annual stockholder meeting;
- allow the authorized number of our directors to be changed from time to time by our stockholders or our board of directors;
- limit the manner in which stockholders can remove directors from our board of directors;
- establish requirements for stockholder proposals that can be acted on at stockholder meetings;
- require that stockholder actions must be effected at a duly called stockholder meeting and allow actions by our stockholders by written consent, with certain requirements;
- limit who may call stockholder meetings; and
- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a "poison pill" that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors.

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. Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the DGCL, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

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.

General Risks

We will incur increased costs and demands upon management as a result of being a newly public company.

As a newly public company listed in the United States, we will incur significant additional legal, accounting and other expenses that we did not incur as a private company. These additional costs could negatively affect our financial results. In addition, changing laws, regulations and standards relating to corporate governance and public disclosure, including regulations implemented by the SEC and Nasdaq, may increase legal and financial compliance costs and make some activities more time consuming. These laws, regulations and standards are subject to varying interpretations and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If notwithstanding our efforts to comply with new laws, regulations and standards, we fail to comply, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

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

If we are unable to design and maintain effective internal control over financial reporting in the future, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock may decline.

We are required to comply with the SEC's rules implementing Sections 302 and 404 of the Sarbanes-Oxley Act, which will require management to certify financial and other information in our quarterly and annual reports and provide an annual management report on the effectiveness of internal control over financial reporting. Although we will be required to disclose changes made in our internal control over financial reporting on a quarterly basis, we will not be required to make our first annual assessment of our internal control over financial reporting until our second Annual Report on Form 10-K.

However, as an emerging growth company, our independent registered public accounting firm will not be required to formally attest to the effectiveness of our internal control over financial reporting until the later of the year following our first annual report required to be filed with the SEC or the date we are no longer an emerging growth company. When we lose our status as an "emerging growth company" and/or 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.

Implementing any appropriate changes to our internal control over financial reporting may distract our officers and employees, entail substantial costs to modify our existing processes and take significant time to complete. These changes may not, however, be effective in establishing and maintaining the adequacy of our internal controls, and any failure to maintain that adequacy or consequent inability to produce accurate financial statements on a timely basis, could increase our operating costs and materially and adversely affect our business, financial condition, results of operations and prospects.

There may be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting once that firm begins its Section 404 reviews, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting or to implement or maintain other effective control systems required of public companies could also restrict our future access to the capital markets.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

As of December 31, 2025, we had federal and state net operating loss, or NOL, carryforwards of $96.6 million and $13.1 million, respectively. Such federal NOL carryforwards may be carried forward indefinitely but are permitted to be used in any taxable year to offset only up to 80% of taxable income in such year, if any. For state income tax purposes, there may be periods during which the use of NOL carryforwards is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. The state NOL carryforwards begin to expire in 2039. In addition, as of December 31, 2025, we had federal research and development tax credits, or R&D credits, of $13.3 million available to offset our future taxable income, if any, which will expire at various dates beginning in 2039.

Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period, the corporation's ability to use its pre-change NOL carryforwards, R&D credits and other tax attributes to offset its post-change income or taxes may be limited. We may have experienced ownership changes in the past, including as a result of our initial public offering and the concurrent private placement, and we may experience ownership changes as a result of subsequent shifts in our stock ownership, some of which may be outside of our control. If an ownership change has occurred or occurs and our ability to use our NOL carryforwards or R&D credits is materially limited, it would harm our future results of operations by effectively increasing our future tax obligations.

Changes in tax laws or regulations may have a material adverse effect on our cash flow, business, financial condition, results of operations or prospects.

New tax laws, statutes, rules, regulations or ordinances could be enacted at any time. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted differently, changed, repealed or modified at any time. Any such enactment, interpretation, change, repeal or modification could adversely affect us, possibly with retroactive effect. For example, the OBBBA (along with prior U.S. federal tax reform legislation) has resulted in significant changes to the taxation of business entities, including, among other changes, the imposition of minimum taxes and excise taxes, changes to the taxation of income derived from international operations, changes in the deduction and amortization of research and development expenditures, and limitations on the deductibility of business interest. Future guidance from the Internal Revenue Service and other tax authorities with respect to these and other legislation may affect us, and certain aspects of such legislation could be repealed or modified in future legislation or sunset in future years. In addition, it is uncertain if and to what extent various states will conform to federal law. We continue to evaluate the impact that these and other tax reforms may have on our business.

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

Our results of operations could be adversely affected by general conditions in the global economy. Unfavorable conditions in the economy both in the United States and abroad, including conditions resulting from changes in gross domestic product growth in the United States or abroad, financial and credit market fluctuations, inflation, fluctuating interest rates, potential tariffs and other concerns regarding international trade relations, political turmoil, natural catastrophes, outbreaks of contagious diseases, warfare and terrorist attacks on the United States, Europe, the Asia Pacific region or elsewhere, such as the conflict in the Middle East, could cause a decrease in business investments, disrupt the timing and cadence of key industry events, and negatively affect the growth of our business and our results of operations. For example, the COVID-19 pandemic adversely affected workforces, economies and financial markets globally, leading to a reduction in the ability of, or the inability of, partners, suppliers, vendors or other parties to meet their contractual obligations, and for a period of time, a reduction in customer spending on technology, and such conditions may reoccur in the future. The war in Ukraine and the related political and economic responses imposed on Russia, such as sanctions, may also exacerbate these issues and trends especially in Europe. A severe or prolonged economic downturn could result in a variety of risks to our business, including weakened demand for our product candidates and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption, or cause delays in payments for our services by third-party payors or our collaborators. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate

and financial market conditions could adversely impact our business, financial condition, results of operations and prospects.

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

We are subject to certain reporting requirements of the Exchange Act. Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements or insufficient disclosures due to error or fraud may occur and not be detected.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

Risk Management and Strategy

We have implemented and maintain various information technology security processes designed to identify, assess, manage, and mitigate material risks stemming from cybersecurity threats to our business, including threats directed to compromising our critical data, intellectual property, and confidential information that is proprietary, strategic or competitive in nature, and clinical trial data, or Information Systems and Data.

Our internal information technology security function, together with third-party service providers, helps identify, assess, manage, and mitigate the Company's cybersecurity threats and risks. Our information technology security function and third-party service providers monitor and evaluate our threat environment using various methods, including, as applicable, automated tools, subscribing to reports and services that identify cybersecurity threats, conducting scans of the threat environment, and evaluating threat reports. Depending on the environment, systems, and data at issue, we implement and maintain various technical, physical, and organizational measures that are intended to manage and mitigate material risks from cybersecurity threats to our Information Systems and Data, including, for example: access controls, physical security, employee training, cybersecurity insurance, incident detection and response, and systems monitoring.

Our assessment and management of material risks from cybersecurity threats are integrated into the Company's overall risk management processes. For example, our information technology security function works with Company management to prioritize our risk management processes and mitigate cybersecurity threats that are likely to lead to a material impact to our business.

We use third-party service providers to perform a variety of functions throughout our business, such as application providers, hosting companies, contract research organizations, and contract manufacturing organizations. We have a vendor management program to manage cybersecurity risks associated with our use of these providers. The program includes reviews of security assessments. 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 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 our Senior Director of Information Security who has over 25 years of experience in cybersecurity, including privacy certifications. Our Senior Director of Information Technology is responsible for hiring appropriate personnel, helping to integrate cybersecurity risk considerations into the Company's overall risk management strategy, and communicating key priorities to relevant personnel. Our Senior Director of Information Technology is 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 processes are designed to escalate certain cybersecurity incidents to members of management depending on the circumstances, including senior management. Security management works with the Company's incident response team to help the Company mitigate and remediate cybersecurity incidents of which they are notified. In addition, the Company's incident response and vulnerability management processes includes reporting to the audit committee of the board of directors for certain cybersecurity incidents.

The audit committee receives periodic reports from our information security function, including our Senior Director of Information Technology, concerning the Company's significant cybersecurity threats and risk and the processes the Company has implemented to address them. The board also has access to various reports, summaries or presentations related to cybersecurity threats, risk and mitigation.

Item 2. Properties.

Our principal executive office is located in Redwood City, California, where we lease a total of 13,734 square feet of office and laboratory space that we use for our administrative, research and development and other activities under a lease that currently expires in 2031. We also lease approximately 6,205 square feet of office space in Burlington, Massachusetts under a lease that expires in 2029, with an option to extend the term for an additional five years. We believe that our facilities are sufficient to meet our current needs and that suitable additional space will be available as and when needed.

Item 3. Legal Proceedings.

From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. We currently are not party to any legal proceedings material to our operations or to which any of our property is the subject, nor are we aware of any such proceedings that are contemplated by a government authority. Regardless of outcome, any such proceedings or claims could have an adverse impact on us because of defense and settlement costs, diversion of resources and other factors and there could be no assurances that any favorable outcomes would be obtained.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

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

Market Information

Our common stock began trading on the Nasdaq Global Select Market on October 27, 2025, under the symbol "MPLT." Prior to that time, there was no public market for our common stock.

Holders of Record

As of March 19, 2026, there were 110 holders of record of our voting common stock. The actual number of stockholders is greater than the number of record holders and does not include beneficial owners of our common stock whose shares are held in "street" name with various dealers, clearing agencies, banks, brokers and other fiduciaries.

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.

Recent Sales of Unregistered Securities

None.

Use of Proceeds from Initial Public Offering of Common Stock

On October 26, 2025, our Registration Statement on Form S-1, as amended (File No. 333-290400), for our initial public offering, or the IPO, became effective, pursuant to which we sold an aggregate of 16,962,500 shares of our common stock for net proceeds of $261.6 million. There has been no material change in the planned use of proceeds from our IPO as described in our prospectus filed pursuant to Rule 424(b)(3) under the Securities Act with the SEC on October 27, 2025.

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 consolidated financial statements and related notes and other financial information included elsewhere in this Annual Report. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report, including information with respect to our plans and strategy for our business, future results of operations and financial position, and our objectives for future operations, includes forward-looking statements that involve risks and uncertainties. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "might," "intend," "target," "ongoing," "project," "estimate," "believe," "estimate," "predict," "potential" or "continue" or the negative of these terms or other similar expressions intended to identify statements about the future. As a result of many factors, including those factors set forth in the section entitled "Risk Factors" of this Annual Report, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis or set forth elsewhere in this Annual Report.

Overview

We are a clinical-stage biopharmaceutical company focused on improving the lives of patients suffering from debilitating central nervous system, or CNS, disorders. We were founded by globally recognized leaders in psychiatry and neuroscience research to address the lack of circuit-specific pharmacotherapies available for patients. Our discovery platform holds the potential to fill this void by identifying neural circuits causally linked to disease and targeting those circuits for therapeutic modulation. We believe our deep understanding of these causal links between the modulation of defined neural circuits and the resulting changes in disease-specific behaviors will enable us to develop therapeutics that can deliver efficacy, safety, tolerability and ease-of-use advantages to patients and prescribers.

Our lead product candidate, ML-007C-MA, is a fixed-dose combination of an M_1/M_4 muscarinic agonist, ML-007, co-formulated with a peripherally acting anticholinergic, or PAC, which we are initially developing for the treatment of schizophrenia and Alzheimer's disease psychosis, or ADP. ML-007C-MA is designed to activate both M_1 and M_4 muscarinic receptors centrally to drive efficacy, while synchronizing the pharmacokinetics of the agonist and antagonist components to mitigate peripheral cholinergic side effects. ML-007 alone, co-administered or co-formulated with the PAC has been evaluated in four Phase 1 trials, with a total of 270 healthy participants enrolled and more than 1,500 doses of ML-007 administered. Based on our clinical and preclinical data, we believe that ML-007C-MA has demonstrated the potential to be a well-tolerated treatment option with convenient dosing, while achieving or exceeding cerebrospinal fluid, or CSF, exposures expected to result in improvement across key symptom domains. We are conducting ZEPHYR, a Phase 2 trial evaluating ML-007C-MA for the treatment of schizophrenia, and we expect the trial to reach the target enrollment of 300 participants in April 2026 and report topline results in the third quarter of 2026. We are also conducting VISTA, a Phase 2 trial evaluating ML-007C-MA for the treatment of ADP, and expect to report topline results in the second half of 2027. In December 2025, ML-007C-MA was granted Fast Track designation by the FDA for the treatment of hallucinations and delusions associated with ADP.

Since our inception in 2018, we have devoted substantially all of our time and efforts to performing research and development activities, raising capital and recruiting management and technical staff to support our operations. To date, we have financed our operations primarily with proceeds from the sales of our redeemable convertible preferred stock and research and development grants received and most recently, with net proceeds from our initial public offering, or IPO, and concurrent private placement.

We have incurred significant net losses since inception. Our net losses for the years ended December 31, 2025 and 2024 were $161.2 million and $77.6 million, respectively. As of December 31, 2025 and 2024, we had an accumulated deficit of $360.5 million and $199.4 million, respectively. We expect to continue to incur significant and increasing expenses and net losses for the foreseeable future as we advance our current and future product candidates through preclinical and clinical development, seek regulatory approval for such product candidates, maintain and expand our intellectual property portfolio, hire additional research and development and business personnel, expand our infrastructure and operate as a public company.

We expect to incur additional costs associated with operating as a public company, including significant legal, accounting, insurance, investor relations and other expenses that we did not incur as a private company. We will not generate revenue from product sales unless and until we successfully complete clinical development and obtain regulatory approval for our product candidates. In addition, if we obtain regulatory approval for our product candidates, we expect to incur significant expenses related to developing our commercialization capability to support product sales, marketing, manufacturing and distribution activities, initially in the United States.

As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of public or private equity offerings and debt financings or other sources, such as potential collaboration agreements, strategic alliances and licensing arrangements. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on acceptable terms, or at all. Our failure to raise capital or enter into such agreements as and when needed could have a material adverse effect on our business, results of operations and financial condition.

At this time, due to the inherently unpredictable nature of clinical and preclinical development and given the current stage of our product candidates, we cannot reasonably estimate the costs we will incur and the timelines that will be required to complete development, obtain marketing approval and commercialize our current or future product candidates, if at all. For the same reasons, we are also unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. If we fail to become profitable or sustain profitability on a continuing basis, then we may be unable to raise additional capital, maintain our research and development efforts, expand our business or continue our operations at planned levels, and as a result we may be forced to substantially reduce or terminate our operations.

As of December 31, 2025, we had cash, cash equivalents and investments of $453.1 million. Based on our current operational plans and assumptions, we expect that our existing cash, cash equivalents and investments will be sufficient to fund our operations through 2027. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we expect. If we are unable to raise sufficient funding, we may be unable to continue to operate in the long term. See "—Liquidity and Capital Resources—Plan of Operation and Future Funding Requirements" below.

NeuroSolis Asset Purchase Agreement

In June 2020, we entered into an Asset Purchase Agreement, or the NeuroSolis Agreement, with NeuroSolis Inc., or NeuroSolis, to acquire NeuroSolis's proprietary M_1/M_4 agonist molecules and associated intellectual property.

Pursuant to the NeuroSolis Agreement, NeuroSolis sold us its assets related to both its proprietary M_1/M_4 agonist molecules and its program for the identification of molecules that modulate the activity of the muscarinic M_1 receptor or the muscarinic M_4 receptor. We did not assume any liabilities of NeuroSolis in connection with our purchase of these assets. We are obligated to use commercially reasonable efforts to achieve specified development and regulatory milestones by developing a product covered by a transferred patent, including ML-007C-MA.

We have made upfront and development milestone payments of $150,000 in the aggregate to NeuroSolis. In addition, we agreed to issue NeuroSolis up to an aggregate of 62,083 shares of our common stock, contingent upon the occurrence of specified development and regulatory milestones, of which 26,607 shares were issued in June 2025.

Stellaromics Agreement

In October 2023, we entered into an Assignment and Assumption Agreement with Stellaromics, Inc., or Stellaromics, an entity focused on developing and commercializing a proprietary three-dimensional transcriptomic device inclusive of a confocal, probes, operating software and sample analysis software, pursuant to which we transferred all our rights and obligations under the licenses for STARmap and other technologies from Stanford University, or the Stellaromics Agreement. In exchange for the transfer of intellectual property, we received an equity investment in Stellaromics common stock and the right to continue using these technologies in devices

already owned. See "—Loss from Equity Method Investment" below and the notes to our consolidated financial statements appearing elsewhere in this Annual Report for information regarding our equity method investment.

Components of Our Results of Operations

Revenue

To date, we have not generated any revenue from any sources, including from product sales, and we do not expect to generate any revenue from the sale of products in the foreseeable future.

Operating Expenses

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for the development of our product candidates and our research activities, including our discovery efforts, and include:

- salaries, benefits and other employee-related costs, including stock-based compensation expense, for personnel engaged in research and development functions;
- expenses incurred under agreements with contract research organizations, or CROs;
- costs of outside consultants, including their fees and travel expenses;
- the costs of laboratory supplies and acquiring, developing and manufacturing preclinical study and clinical trial materials;
- the costs associated with clinical trials; and
- facility-related expenses, which include direct depreciation costs and allocated expenses for rent and maintenance of facilities and other operating costs.

We expense research and development costs as incurred. Costs for external development activities are recognized based on an evaluation of the progress to completion of specific activities. Payments for these activities are based on the terms of the individual agreements, which may differ from the timing of costs incurred, and are reflected in our consolidated financial statements as prepaid or accrued research and development expenses.

We typically use our employee and infrastructure resources across our development programs and therefore we do not allocate personnel costs, license payments made under our licensing arrangements or other internal costs to specific development programs or product candidates. We also do not track external expenses by specific development program or product candidate.

Research and development activities are central to our business model. We expect that our research and development expenses will continue to increase substantially for the foreseeable future as we initiate and conduct clinical trials, advance our preclinical programs and continue to discover and develop additional product candidates.

The process of conducting the necessary preclinical and clinical research to obtain regulatory approval is costly and time consuming. We cannot reasonably estimate the nature, timing and estimated costs of the efforts that will be necessary to complete development of our current or future product candidates. There are numerous risks and uncertainties associated with the duration and cost of successfully developing product candidates, which can vary significantly, including:

- successful and timely completion of preclinical studies;
- initiation and successful patient enrollment in, and completion of, clinical trials on a timely basis;
- gaining agreement on the design, endpoints and implementation of preclinical studies and clinical trials with the U.S. Food and Drug Administration, or the FDA, or any comparable foreign regulatory authority;
- sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials;

- receiving regulatory approvals or authorizations for conducting future clinical trials;
- our ability to demonstrate to the satisfaction of the FDA or any comparable foreign regulatory authority that the applicable product candidate is safe and effective as for its intended uses;
- our ability to demonstrate to the satisfaction of the FDA or any comparable foreign regulatory authority that the applicable product candidate's risk-benefit ratio for its proposed indication is acceptable;
- timely receipt of marketing approvals for our product candidates from applicable regulatory authorities;
- the extent of any required post-marketing approval commitments to applicable regulatory authorities;
- establishing and scaling up, either alone or with third-party manufacturers, manufacturing capabilities of clinical supply for our clinical trials and commercial manufacturing, if any of our product candidates are approved;
- effectively competing with other therapies available on the market or in development; and
- successfully identifying and developing, acquiring or in-licensing additional product candidates to expand our pipeline.

A change in the outcome of any of these variables with respect to the development of our current and future product candidates may significantly change the costs and timing associated with the development of those product candidates and we may never succeed in achieving regulatory approval for any of our product candidates. As a result of these uncertainties, we are unable to precisely forecast the duration and completion costs of our research and development activities.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries, benefits and other related costs, including stock-based compensation, for personnel in our executive, finance, business development and administrative functions. General and administrative expenses also include legal fees relating to intellectual property and corporate matters; professional fees for accounting, auditing, tax and consulting services; insurance costs; travel expenses; and facility-related expenses, which include direct depreciation costs and allocated expenses for rent and maintenance of facilities and other operating costs.

We expect that our general and administrative expenses will increase in the future as we increase our personnel headcount to support our continued clinical development efforts, research and development activities, manufacturing activities and related expansion of our operations. We also anticipate increased expenses associated with being a public company, including costs for audit, legal, regulatory and tax-related services related to compliance with the rules and regulations of the Securities and Exchange Commission, or SEC, and the listing standards of the Nasdaq Stock Market LLC, or Nasdaq, director and officer insurance premiums and investor relations costs.

Other Income (Expense), Net

Interest Income

Interest income consists of interest income earned on our cash, cash equivalents and investments.

Loss from Equity Method Investment

In October 2023, we entered into the Stellaromics Agreement. As of December 31, 2025, we held approximately 3.7% of the outstanding capital stock of Stellaromics. Additionally, Christopher A. Kroeger, M.D., our Chief Executive Officer and a member of our board of directors, and George Pavlov, one of our directors, are members of Stellaromics' board of directors, and our largest stockholder, Catalyst4, Inc., holds greater than 70.0% of the outstanding capital stock of Stellaromics. We have significant influence over, but do not control, Stellaromics through our noncontrolling representation on Stellaromics' board of directors and our equity interest in Stellaromics. We determined that Stellaromics is a variable interest entity because it does not have sufficient equity at risk to

finance its operations without additional subordinated financial support. We are not the primary beneficiary as we do not have the power to direct activities that most significantly impact Stellaromics' economic performance. Accordingly, we do not consolidate the financial statements of Stellaromics and account for this investment using the equity method of accounting.

Under the equity method of accounting, our investments are initially recorded at fair value on our consolidated balance sheets. Upon recording an equity method investment, we evaluate whether there are basis differences between the carrying value and fair value of our proportionate share of the investee's underlying net assets. Typically, we amortize identified basis differences on a straight-line basis over the underlying asset's or liability's estimated useful life when calculating the attributable earnings or losses. If we are unable to attribute all of the basis difference to specific assets or liabilities of the investee, we consider the residual excess of the cost of the investment over the proportional fair value of the investee's assets and liabilities to be equity method goodwill, which is recognized within the equity investment balance. We subsequently record in the consolidated statements of operations and comprehensive loss our share of income or loss of the other entity within the equity method investment, net line item.

We evaluate our equity method investments for impairment whenever events or changes in circumstances indicate that the carrying amounts of such investments may be impaired and consider qualitative and quantitative factors including the investee's financial metrics, product and commercial outlook and cash usage. If a decline in the value of an equity method investment is determined to be other than temporary, a loss is recorded in earnings in the current period and the investment is written down to fair value.

Other Income, Net

Other income, net consists primarily of amortization of premiums and accretion of discounts to maturity for available-for-sale debt securities.

Income Taxes

Since our inception, we have not recorded income tax benefits for the net operating losses, or NOLs, incurred or the research and development tax credits generated in each year due to the uncertainty of realizing a benefit from those items. As of December 31, 2025, we had U.S. federal and state net operating loss carryforwards of $96.6 million and $13.1 million, respectively, which may be available to offset future taxable income. The federal net operating loss carryforwards do not expire, but may only be used to offset 80% of annual taxable income. The state net operating loss carryforwards expire beginning in 2039. As of December 31, 2025, we also had federal and state research and development tax credit carryforwards of $13.3 million and $0.2 million, respectively.

Results of Operations

Comparison of the years ended December 31, 2025 and 2024

The following table summarizes our results of operations for the periods indicated (in thousands):

	Year Ended December 31,		
	2025	2024	Change
Operating expenses:			
Research and development	$ 138,349	$ 68,523	$ 69,826
General and administrative	30,734	14,423	16,311
Total operating expenses	169,083	82,946	86,137
Loss from operations	(169,083)	(82,946)	(86,137)
Other income (expense), net:			
Interest income	5,518	4,504	1,014
Loss from equity method investment	—	(986)	986
Other income, net	2,413	1,848	565
Total other income, net	7,931	5,366	2,565
Net loss	$ (161,152)	$ (77,580)	$ (83,572)

Research and Development Expenses

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

	Year Ended December 31,		
	2025	2024	Change
Clinical trial expenses	$ 53,461	$ 18,180	$ 35,281
Employee-related expenses	51,062	21,337	29,725
Chemistry, manufacturing and controls expenses	18,266	11,473	6,793
Preclinical program expenses	10,421	13,972	(3,551)
Other expenses	5,139	3,561	1,578
Total	$ 138,349	$ 68,523	$ 69,826

Research and development expenses were $138.3 million for the year ended December 31, 2025, compared to $68.5 million for the year ended December 31, 2024. The increase in total research and development expenses of $69.8 million was primarily due to an increase of $35.3 million in clinical trial expenses; an increase of $29.7 million in employee-related expenses, including an increase in stock-based compensation expense of $21.6 million, primarily related to the vesting of restricted stock units in connection with the effectiveness of the IPO; and an increase of $6.8 million in chemistry, manufacturing and controls, or CMC, expenses; offset by a decrease of $3.6 million in preclinical program expenses. Research and development expenses were reduced due to grant earnings of $3.2 million and $1.0 million recognized for the years ended December 31, 2025 and 2024, respectively.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the periods indicated (in thousands):

	Year Ended December 31,		
	2025	2024	Change
Employee-related expenses	$ 21,688	$ 7,457	$ 14,231
Professional fees and other expenses	9,046	6,966	2,080
Total	$ 30,734	$ 14,423	$ 16,311

General and administrative expenses were $30.7 million for the year ended December 31, 2025, compared to $14.4 million for the year ended December 31, 2024. The increase in total general and administrative expenses of $16.3 million was due primarily due to an increase of $14.2 million in employee-related expenses, including an increase in stock-based compensation expense of $13.3 million, primarily related to the vesting of restricted stock units in connection with the effectiveness of the IPO; and an increase of $2.1 million in professional fees and other expenses.

Other Income (Expense), Net

Interest Income

Interest income was $5.5 million for the year ended December 31, 2025, compared to $4.5 million for the year ended December 31, 2024. The increase in interest income of $1.0 million was due to an increase in short-term and long-term investments held during the year ended December 31, 2025 compared to the year ended December 31, 2024.

Loss from Equity Method Investment

The loss from equity method investment of $1.0 million recognized during the year ended December 31, 2024 was due to recognition of the loss from equity method investment related to our investment in Stellaromics. As of year ended December 31, 2025, the carrying value of the equity method investment was $0, and no further losses will be recorded because we do not have any obligation to fund future losses.

Other Income, Net

Other income, net was $2.4 million for the year ended December 31, 2025, compared to $1.8 million for the year ended December 31, 2024. The increase of $0.6 million was primarily due to increased amortization of premiums and accretion of discounts on investments held during the year ended December 31, 2025.

Liquidity and Capital Resources

Sources of Liquidity

We have incurred significant net losses since inception. We expect to continue to incur significant and increasing expenses and net losses for the foreseeable future as we advance our current and future product candidates through preclinical and clinical development, seek regulatory approval for our current and future product candidates through clinical and preclinical development, maintain and expand our intellectual property portfolio, hire additional research and development and business personnel, scale-up our production capabilities and operate as a public company. As of December 31, 2025, we had cash, cash equivalents and investments of $453.1 million and an accumulated deficit of $360.5 million. Historically, we have financed our operations primarily through issuances of our redeemable convertible preferred stock and research and development grants, and more recently, with proceeds from our IPO and concurrent private placement.

In October 2025, we closed our IPO, pursuant to which we issued and sold an aggregate of 16,962,500 shares of our common stock at a public offering price of $17.00 per share for gross proceeds of $288.4 million. The aggregate net proceeds from our IPO, including the exercise by the underwriters of their option to purchase additional shares, were $261.6 million, after deducting underwriting discounts and commissions and offering expenses. Concurrent with our IPO, we also closed our concurrent private placement, or Concurrent Private Placement, in which we issued and sold 476,707 shares of our common stock at a price of $17.00 per share. We received aggregate net proceeds of $7.5 million from our Concurrent Private Placement, after deducting placement agent fees and private placement expenses.

Cash Flows

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

	Year Ended December 31,		
	2025	2024	Change
Net cash (used in) provided by:			
Operating activities	$ (138,137)	$ (78,815)	$ (59,322)
Investing activities	(323,207)	(80,788)	(242,419)
Financing activities	469,820	118,060	351,760
Total	$ 8,476	$ (41,543)	$ 50,019

Operating Activities

Our cash flows from operating activities are primarily driven by our use of cash for operating expenses and working capital required to support our business. We have historically generated negative cash flows from operating activities due to expenses incurred for our clinical trials, preclinical studies, and research and development initiatives.

Net cash used in operating activities was $138.1 million for the year ended December 31, 2025, reflecting a net loss of $161.2 million and a net change in our net operating assets and liabilities of $12.8 million, partially offset by non-cash charges of $35.9 million. The change in our net operating assets and liabilities was primarily due to a $13.1 million increase in prepaid expenses and other assets, a $3.2 million decrease in deferred grant earnings and a $0.8 million decrease in operating lease liability, offset by a $2.9 million increase in accrued expenses and a $1.4 million increase in accounts payable. Non-cash charges primarily consisted of $36.0 million of stock-based compensation expense, $0.9 million of non-cash lease expense, $0.6 million of depreciation and $0.5 million of common stock issued to NeuroSolis, offset by $2.1 million of net amortization of premiums and accretion of discounts on investments.

Net cash used in operating activities was $78.8 million for the year ended December 31, 2024, reflecting a net loss of $77.6 million and a net change in our net operating assets and liabilities of $3.1 million, partially offset by non-cash charges of $1.8 million. The change in our net operating assets and liabilities was primarily due to a $2.3 million increase in prepaid expenses and other assets and a $1.3 million decrease in accounts payable, partially offset by a $2.2 million increase in accrued expenses. Non-cash charges primarily consisted of stock-based compensation expense of $1.1 million and a loss on equity method investment of $1.0 million, partially offset by net amortization of premiums and accretion of discounts on investments of $1.7 million.

Investing Activities

Net cash used in investing activities was $323.2 million for the year ended December 31, 2025, compared to net cash used in investing activities of $80.8 million for the year ended December 31, 2024. The increase in cash used in investing activities during the year ended December 31, 2025 was driven by the purchases of short-term and long-term investments.

Financing Activities

Net cash provided by financing activities was $469.8 million for the year ended December 31, 2025, compared to net cash provided by financing activities of $118.1 million for the year ended December 31, 2024. The increase in cash provided by financing activities was primarily due to net proceeds received from our IPO, the Concurrent Private Placement and the issuance and sale of shares of our Series D redeemable convertible preferred stock, net of issuance costs during the year ended December 31, 2025.

Plan of Operation and Future Funding Requirements

We use our capital resources mainly to fund operating expenses, including research and development expenditures. We plan to increase our research and development expenses for the foreseeable future as we continue

clinical trial activities, advance our preclinical programs into the clinic and continue to discover and develop additional product candidates. At this time, due to the inherently unpredictable nature of clinical and preclinical development and given the early stage of our product candidates, we cannot reasonably estimate the costs we will incur and the timelines that will be required to complete development, obtain marketing approval and commercialize our current product candidates or any future product candidates, if any. For the same reasons, we are also unable to predict when, if ever, we will generate revenue from product sales or whether, or when, if ever, we may achieve profitability. Clinical and preclinical development timelines, the probability of success, and development costs can differ materially from expectations. In addition, we cannot forecast which product candidates may be subject to future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements.

As of December 31, 2025, we had cash, cash equivalents and investments of $453.1 million. Based on our current operational plans and assumptions, we expect that our existing cash, cash equivalents and investments will be sufficient to fund our operations through 2027. We have based this estimate on assumptions that may prove to be wrong, however, and we could use our capital resources sooner than we expect.

The timing and amount of our operating expenditures will depend largely on:

- 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;
- 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 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 enter into and maintain 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, market access, sales and distribution, for any of our product candidates for which we receive marketing approval;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- expenses to attract, hire and retain skilled personnel;
- 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;
- addressing any potential supply chain interruptions or delays;
- our ability to mitigate the impact of adverse macroeconomic conditions or geopolitical events, including the ongoing conflicts between Ukraine and Russia and in the Middle East, bank failures, inflation and increased interest rates or other factors 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 business, products, and technologies.

Our existing cash, cash equivalents and investments will not be sufficient to complete development of any product candidate. Accordingly, we will be required to obtain further funding to achieve our business objectives.

Until we can generate substantial revenue from product sales, if ever, we expect to finance our operations through a combination of public or private equity offerings and debt financings. We may also consider entering into collaborations, strategic alliances and licensing arrangements or selectively partnering for clinical development and commercialization as well as funding through other sources. The sale of additional equity may result in additional dilution to our stockholders. The incurrence of debt financing would result in debt service obligations, and the instruments governing such debt could provide for operating and financial covenants that could restrict our operations or our ability to incur additional indebtedness or pay dividends, among other things. If we raise additional funds through governmental funding, collaborations, strategic partnerships and 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 not able to secure adequate additional funding, we may be forced to make reductions in spending, extend payment terms with suppliers, liquidate assets where possible and/or suspend or curtail planned programs or cease operations. Any of these actions could materially and adversely affect our business, financial condition, results of operations and prospects.

Contractual Obligations

Leases

In August 2020, we entered into a lab and office lease agreement in Redwood City, California. We rented additional space under amendments to the lease agreement in August 2022 and August 2023. We currently lease a total of 13,734 square feet and the term of the lease extends to June 2031. The lease provides for escalating annualized base rent payments starting at $0.8 million and increasing to $1.2 million in the final year of the lease. Remaining lease payments from January 1, 2026 through the end of the lease term total $6.0 million.

In September 2023, we entered into a lease agreement for office space located in Burlington, Massachusetts. This lease commenced in April 2024 and has an initial term of approximately five years, with an option to extend the term for an additional five years. Cash that is required to be held as a security deposit in accordance with the lease is $0.2 million. Remaining lease payments from January 1, 2026 through the end of the lease term total $1.1 million.

Purchase and Other Obligations

We enter into contracts in the normal course of business with CROs and other vendors to assist in the performance of our clinical trials, CMC, research and development and other services and products for operating purposes. These contracts typically do not contain minimum purchase commitments and generally provide for termination on notice. Payments due upon cancellation consist of payments for services provided or expenses incurred to date, including payment of noncancelable obligations of our service providers, up to the date of cancellation, and may also include termination penalties. As of December 31, 2025, the timing, amount or likelihood of such payments are not known.

Grant and License Agreements

We are party to certain grant agreements with the Michael J. Fox Foundation and license and collaboration agreements with NeuroSolis, Stanford University, Vanderbilt University and other third parties. We may be obligated to make certain future payments under these agreements that are contingent upon future events such as our achievement of specified preclinical, clinical, regulatory and commercial milestones or royalties on net product sales under these agreements. As of December 31, 2025, we were unable to estimate the timing or likelihood of achieving these milestones or generating future product sales.

Critical Accounting Policies and Use of Estimates

This discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements included elsewhere in this Annual Report, which have been prepared in accordance with generally accepted accounting principles in the United States. The preparation of our financial statements and related disclosures requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, costs and expenses and the disclosure of contingent assets and liabilities in our financial statements. We

base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in Note 2 in our consolidated financial statements included elsewhere in this Annual Report, we believe that our critical accounting estimates are as follows.

Research and Development Expense and Accruals

In preparing the consolidated financial statements, we estimate amounts related to accrued research and development expenses. This process involves reviewing open contracts and purchase orders, communicating with personnel and contract research organizations, or CROs, to identify services that have been performed on our behalf and estimating the level of service performed and the associated costs incurred for the services when we have not yet been invoiced or otherwise notified of the actual costs. The majority of research and development service providers invoice in arrears for services performed, on a predetermined schedule or when contractual milestones are met; however, some require advanced payments. We make estimates of accrued expenses as of each consolidated balance sheet date in the consolidated financial statements based on facts and circumstances known to at that time. Examples of estimated accrued research and development expenses include fees paid to:

- CROs in connection with performing research services and clinical trials on our behalf;
- investigative sites or other providers in connection with clinical trials;
- vendors in connection with preclinical and clinical development activities; and
- vendors related to product manufacturing, development and distribution of preclinical and clinical material and supplies.

Expenses relate to preclinical studies and clinical trials based on estimates of the services received and efforts expended pursuant to quotes and contracts with multiple CROs that conduct and manage clinical trials 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 vendors will exceed the level of services provided and result in a prepayment of the preclinical and clinical expenses. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing service fees, we estimate the time period over which services will be performed, enrollment of patients, number of sites activated and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, we adjust the accrual or amount of prepaid expense accordingly. Although we do not expect the estimates to be materially different from amounts actually incurred, the understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in us reporting amounts that are too high or too low in any particular period. To date, we have not made any material adjustments to prior estimates of accrued research and development expenses.

Stock-Based Compensation

We account for stock-based compensation in accordance with ASC 718, *Compensation—Stock Compensation*, or ASC 718. ASC 718 requires all share-based payments to employees and directors to be recognized as expense in the consolidated statement of operations and comprehensive loss based on their grant date fair values. We estimate the fair value of options granted using the Black-Scholes option pricing model for stock option grants to both employees and non-employees. We believe the fair value of the stock options granted to non-employees is more reliably determinable than the fair value of the services provided.

The Black-Scholes option pricing model requires inputs based on certain subjective assumptions, including (a) the stock price, (b) the expected volatility, (c) the expected term of the award, (d) the risk-free interest rate and (e) expected dividends. Prior to the IPO, our board of directors determined the fair value of our common stock, taking

into consideration our most recently available third-party valuations of common stock as well as additional factors which may have changed since the date of the most recent contemporaneous valuation through the grant date. We have historically been a private company that lacked company-specific historical and implied volatility information. Following the IPO, the fair value of our common stock is determined based on the quoted market price of common stock. The historical volatility is calculated based on a period of time commensurate with the expected term assumption. We use the simplified method as prescribed by the SEC Staff Accounting Bulletin No. 107, Share-Based Payment, to calculate the expected term for options granted to employees as we do not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term. The expected term is applied to the stock option grant group as a whole, as we do not expect substantially different exercise or post-vesting termination behavior among our employee population. For options granted to non-employees, we utilize the contractual term of the share-based payment as the basis for the expected term assumption. The risk-free interest rate is based on a treasury instrument whose term is consistent with the expected term of the stock options. The expected dividend yield is assumed to be zero as we have never paid dividends and have no current plans to pay any dividends on common stock.

There are significant judgments and estimates inherent in the determination of the fair value of common stock. These estimates and assumptions include a number of objective and subjective factors, including external market conditions and the prices at which we sold shares of redeemable convertible preferred stock.

We expense the fair value of share-based compensation awards to employees and non-employees that have time-based vesting criteria on a straight-line basis over the requisite service period, which is generally the vesting period. Forfeitures are recognized as they occur. We expense the fair value of share-based compensation awards to employees and non-employees that have performance-based vesting criteria when the performance condition is considered probable of achievement, using management’s best estimates, which consider the inherent risk and uncertainty regarding the future outcomes of the milestones.

Recent Accounting Pronouncements

For a description of recent accounting pronouncements, see Note 2 to our consolidated financial statements appearing elsewhere in this Annual Report.

Emerging Growth Company and Smaller Reporting Company Status

The JOBS Act provides that, among other things, 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. As an emerging growth company, we have elected to take advantage of the extended transition period to comply with new or revised accounting standards and to adopt certain of the reduced disclosure requirements available to emerging growth companies. As a result of the accounting standards election, we will not be subject to the same implementation timing for new or revised accounting standards as other public companies that are not emerging growth companies, which may make comparison of our financials to those of other public companies more difficult. We may choose to early adopt any new or revised accounting standards whenever such early adoption is permitted for private companies. We intend to rely on certain of the other exemptions and reduced reporting requirements provided by the JOBS Act. As an emerging growth company, we are not required to, among other things, (i) provide an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404(b), and (ii) comply with any requirement that may be adopted by the PCAOB regarding a supplement to the auditor's report providing additional information about the audit and the financial statements (auditor discussion and analysis).

We will remain an emerging growth company until the earliest of (i) December 31, 2030, (ii) the last day of the fiscal year in which we have total annual gross revenue of at least $1.235 billion, (iii) the last day of the fiscal year in which we are deemed to be a "large accelerated filer" as defined in Rule 12b-2 under the Exchange Act of 1934, as amended, or the Exchange Act, which would occur if the market value of our common stock held by non-affiliates exceeded $700 million as of the last business day of the second fiscal quarter of such year (and we have been a public company for at least 12 months and have filed one annual report on Form 10-K) or (iv) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period.

We are also a "smaller reporting company," as defined in Rule 12b-2 under the Exchange Act. 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 million or (ii) our annual revenue is less than $100 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700 million.

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.

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

As a "smaller reporting company" as defined by Item 10 of Regulation S-K, we are not required to provide quantitative and qualitative disclosures about market risk.

Item 8. Financial Statements and Supplementary Data.

Our consolidated financial statements for the years ended December 31, 2025 and 2024, together with the reports of our independent registered public accounting firms, appear beginning on page F-1 of this Annual Report on Form 10-K.

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

Our management, including our principal executive officer and our principal financial officer, conducted an evaluation of the effectiveness of our disclosure controls and procedures as of December 31, 2025, the end of the period covered by this Annual Report on Form 10-K. The term "disclosure controls and procedures," as set forth in Rules 13a-15(e) and 15d-15(e) under the Exchange Act means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the rules and forms promulgated by the SEC. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2025, our principal executive officer and principal financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Annual Report on Internal Control Over Financial Reporting

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

Attestation Report of the Registered Public Accounting Firm

This Annual Report does not include an attestation report of our independent registered public accounting firm due to a transition period established by rules of the SEC for newly public companies.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) 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.

Rule 10b5-1 Trading Arrangements

The following table contains information about the "Rule 105b-1 trading arrangements" that were adopted by our directors and executive officers during the fiscal quarter ended December 31, 2025:

Name (Title)	Action Taken (Date of Action)	Nature of Trading Arrangement	Expiration Date of Trading Arrangement[(1)]	Aggregate Number of Securities
Erin Pennock Foff, M.D., Ph.D. (Chief Medical Officer)	Adoption (December 29, 2025)	Sale	September 30, 2026	Up to 105,657
Jonathan Gillis (Chief Administrative and Accounting Officer)	Adoption (December 26, 2025)	Sale	September 30, 2026	Up to 132,454[(2)]
Kristopher L. Hanson (General Counsel)	Adoption (December 29, 2025)	Sale	September 30, 2026	Up to 54,485
Anatol Kreitzer, Ph.D. (Chief Discovery Officer)	Adoption (December 24, 2025)	Sale	September 30, 2026	Up to 127,121[(2)]
Christopher A. Kroeger, M.D. (Chief Executive Officer and Director)	Adoption (December 29, 2025)	Sale	September 30, 2026	Up to 384,298
James Lillie, Ph.D. (Chief Scientific Officer)	Adoption (December 29, 2025)	Sale	September 30, 2026	Up to 74,510
Robert Malenka, M.D., Ph.D. (Director)	Adoption (December 26, 2025)	Sale	December 31, 2026	Up to 101,575[(2)]
Vishwas Setia (Chief Financial Officer)	Adoption (December 29, 2025)	Sale	September 30, 2026	Up to 75,371

(1) A trading arrangement may expire on an earlier date if all contemplated transactions are completed before such trading arrangement's expiration date, upon termination by the applicable broker or the holder of the trading arrangement, or as otherwise provided in the trading arrangement.

(2) The Aggregate Number of Securities includes unvested restricted stock units for which shares of common stock will be withheld or sold to cover applicable taxes due with respect to the settlement of the restricted stock units.

Except as set forth above, none of our directors or executive officers adopted, modified or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule-10b5-1 trading arrangement," as each term is defined in Item 408(a) of Regulation S-K, during the fiscal quarter ended December 31, 2025.

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 will be included in our proxy statement with respect to our 2026 Annual Meeting of Stockholders, which we intend to file within 120 days after the end of our 2025 fiscal year, under the headings “Election of Directors,” “Executive Officers,” “Corporate Governance and Board Matters” and “Delinquent Section 16(a) Reports,” if applicable, and is incorporated herein by reference.

Item 11. Executive Compensation.

The information required by this item will be included in our proxy statement with respect to our 2026 Annual Meeting of Stockholders, which we intend to file within 120 days after the end of our 2025 fiscal year, under the headings “Executive Compensation” and “Director Compensation” 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 be included in our proxy statement with respect to our 2026 Annual Meeting of Stockholders, which we intend to file within 120 days after the end of our 2025 fiscal year, under the headings “Security Ownership of Certain Beneficial Owners and Management” and “Executive Compensation—Equity Compensation Plan Information” 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 proxy statement with respect to our 2026 Annual Meeting of Stockholders, which we intend to file within 120 days after the end of our 2025 fiscal year, under the headings “Transactions with Related Persons and Indemnification” and “Corporate Governance and Board Matters—Independence of the Board of Directors” and is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services.

The information required by this item will be included in our proxy statement with respect to our 2026 Annual Meeting of Stockholders, which we intend to file within 120 days after the end of our 2025 fiscal year, under the heading “Ratification of Appointment of Independent Registered Public Accounting Firm” and is incorporated herein by reference.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(a) List of Documents filed as part of this Report

(1) For a list of the financial statements included herein, see Index to the Consolidated Financial Statements on page F-1 of this Annual Report, incorporated into this Item by reference.

(2) Financial statement schedules have been omitted because they are either not required or not applicable or the information is included in the consolidated financial statements or the notes thereto.

(3) Exhibits:

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation of the Registrant (incorporated herein by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-42914) filed with the SEC on October 29, 2025)
3.2	Amended and Restated Bylaws of the Registrant (incorporated herein by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K (File No. 001-42914) filed with the SEC on October 29, 2025)
4.1^	Amended and Restated Investors' Rights Agreement, by and among the Registrant and certain of its stockholders, dated July 18, 2025 (incorporated herein by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1 (File No. 333-290400) filed with the SEC on September 19, 2025)
4.2*	Description of Registrant's Securities
10.1+	2019 Equity Incentive Plan and Forms of Stock Option Agreement and Notice of Exercise and Restricted Stock Unit Grant Notice and Restricted Stock Award Agreement (incorporated herein by reference to Exhibit 10.1 to the Registrant's Registration Statement on Form S-1 (File No. 333-290400) filed with the SEC on September 19, 2025)
10.2+	2025 Equity Incentive Plan and Forms of Stock Option Grant Notice, Stock Option Agreement, Notice of Exercise, Restricted Stock Unit Grant Notice and Restricted Stock Unit Award Agreement (incorporated herein by reference to Exhibit 10.2 to the Registrant's Registration Statement on Form S-1/A (File No. 333-290400) filed with the SEC on October 6, 2025)
10.3+	2025 Employee Stock Purchase Plan (incorporated herein by reference to Exhibit 10.3 to the Registrant's Registration Statement on Form S-1/A (File No. 333-290400) filed with the SEC on October 6, 2025)
10.4+	Form of Indemnification Agreement with Executive Officers and Directors (incorporated herein by reference to Exhibit 10.4 to the Registrant's Registration Statement on Form S-1 (File No. 333-290400) filed with the SEC on September 19, 2025)
10.5+	Confirmatory Offer Letter Agreement by and between the Registrant and Christopher A. Kroeger, M.D. (incorporated herein by reference to Exhibit 10.5 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-42914) filed with the SEC on December 4, 2025)
10.6+	Confirmatory Offer Letter Agreement by and between the Registrant and Vishwas Setia (incorporated herein by reference to Exhibit 10.6 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-42914) filed with the SEC on December 4, 2025)
10.7+	Confirmatory Offer Letter Agreement by and between the Registrant and Erin Pennock Foff, M.D., Ph.D. (incorporated herein by reference to Exhibit 10.7 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-42914) filed with the SEC on December 4, 2025)
10.8+	Advisor Agreement by and between the Registrant and Robert Malenka, M.D., Ph.D., dated February 25, 2019 (incorporated herein by reference to Exhibit 10.9 to the Registrant's Registration Statement on Form S-1 (File No. 333-290400) filed with the SEC on September 19, 2025)
10.9*+	First Amendment to Advisor Agreement by and between the Registrant and Robert Malenka, M.D., Ph.D., dated January 1, 2026
10.10+^	Severance and Change in Control Plan (incorporated herein by reference to Exhibit 10.10 to the Registrant's Registration Statement on Form S-1 (File No. 333-290400) filed with the SEC on September 19, 2025)
10.11*+	Non-Employee Director Compensation Policy

10.12†	Asset Purchase Agreement by and between the Registrant and NeuroSolis, Inc. dated June 18, 2020 (incorporated herein by reference to Exhibit 10.8 to the Registrant's Registration Statement on Form S-1 (File No. 333-290400) filed with the SEC on September 19, 2025)
19.1*	Insider Trading Policy
21.1	List of Subsidiaries (incorporated herein by reference to Exhibit 21.1 to the Registrant's Registration Statement on Form S-1 (File No. 333-290400) filed with the SEC on September 19, 2025)
23.1*	Consent of RSM US LLP, independent registered public accounting firm
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.
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.
32.1#	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
97.1*	Incentive Compensation Recoupment Policy
101.INS	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)

* Filed herewith.

\# This certification is being furnished solely to accompany this Annual Report pursuant to 18 U.S.C. Section 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is 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.

\+ Indicates management contract or compensatory plan.

† Portions of this exhibit (indicated by asterisks) have been redacted in compliance with Regulation S-K Item 601(b)(10)(iv) because the Registrant has determined that the information is both not material and is the type that the Registrant treats as private or confidential.

^ Certain schedules and exhibits to this exhibit have been omitted pursuant to Item 601(a)(5) of Regulation S-K. A copy of any omitted schedule and/or exhibit will be furnished to the SEC upon request.

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.

MapLight Therapeutics, Inc.

Date: March 26, 2026 By: /s/ Christopher A. Kroeger
Christopher A. Kroeger, M.D.
Chief Executive Officer

Date: March 26, 2026 By: /s/ Vishwas Setia
Vishwas Setia
Chief Financial Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Name	Title	Date
/s/ Christopher A. Kroeger **Christopher A. Kroeger, M.D.**	Chief Executive Officer and Director *(Principal Executive Officer)*	March 26, 2026
/s/ Vishwas Setia **Vishwas Setia**	Chief Financial Officer *(Principal Financial Officer)*	March 26, 2026
/s/ Jonathan Gillis **Jonathan Gillis**	Chief Administrative and Accounting Officer *(Principal Accounting Officer)*	March 26, 2026
/s/ Timothy Garnett **Timothy Garnett, M.B.B.S.**	Director	March 26, 2026
/s/ Nanna Lüneborg **Nanna Lüneborg, Ph.D.**	Director	March 26, 2026
/s/ Robert Malenka **Robert Malenka, M.D., Ph.D.**	Director	March 26, 2026
/s/ George Pavlov **George Pavlov**	Director	March 26, 2026
/s/ Jim Trenkle **Jim Trenkle, Ph.D.**	Director	March 26, 2026
/s/ Maria Walker **Maria Walker**	Director	March 26, 2026

Index to Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of MapLight Therapeutics, Inc.

Opinion on the Financial Statements
We have audited the accompanying consolidated balance sheets of MapLight Therapeutics, Inc. and its subsidiary (the Company) as of December 31, 2025 and 2024, the related consolidated statements of operations and comprehensive loss, redeemable convertible preferred stock and stockholders' equity (deficit) and cash flows for the years then ended, and the related notes to the consolidated financial statements (collectively, the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2025 and 2024, and the results of its operations and its cash flows for 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 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/ RSM US LLP

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

Boston, Massachusetts
March 26, 2026

MapLight Therapeutics, Inc.
Consolidated Balance Sheets
(in thousands, except share and per share amounts)

	December 31,	
	2025	**2024**
Assets		
Current assets:		
Cash and cash equivalents	$ 46,729	$ 38,253
Short-term investments	258,374	70,542
Prepaid expenses and other current assets	19,567	5,807
Total current assets	324,670	114,602
Property and equipment, net	1,095	1,207
Long-term investments	147,993	11,380
Restricted cash	207	207
Right-of-use asset	5,488	6,354
Other assets	59	3,166
Total assets	$ 479,512	$ 136,916
Liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 3,289	$ 1,912
Accrued expenses	12,049	9,991
Lease liability - current	891	778
Deferred grant earnings	—	3,239
Total current liabilities	16,229	15,920
Lease liability - noncurrent	4,911	5,801
Total liabilities	21,140	21,721
Commitments and contingencies (Note 15)		
Redeemable convertible preferred stock:		
Series C redeemable convertible preferred stock, $0.0001 par value; 0 and 147,325,537 shares authorized at December 31, 2025 and 2024, respectively; 0 and 147,325,527 shares issued and outstanding at December 31, 2025 and 2024, respectively	—	224,992
Series B-1 redeemable convertible preferred stock, $0.0001 par value; 0 and 4,622,496 shares authorized, issued and outstanding at December 31, 2025 and 2024, respectively	—	11,981
Series B redeemable convertible preferred stock, $0.0001 par value; 0 and 45,010,383 shares authorized, issued and outstanding at December 31, 2025 and 2024, respectively	—	51,094
Series A-1 redeemable convertible preferred stock, $0.0001 par value; 0 and 14,946,844 shares authorized, issued and outstanding at December 31, 2025 and 2024, respectively	—	15,963
Series A redeemable convertible preferred stock, $0.0001 par value; 0 and 5,000,000 shares authorized, issued and outstanding at December 31, 2025 and 2024, respectively	—	4,793
Stockholders' equity (deficit):		
Preferred stock, $0.0001 par value; 10,000,000 and 0 shares authorized at December 31, 2025 and 2024, respectively; 0 shares issued and outstanding at December 31, 2025 and 2024	—	—
Common stock, $0.0001 par value; and 500,000,000 and 325,000,000 shares authorized as of December 31, 2025 and 2024, respectively; 44,024,088 and 761,276 shares issued and outstanding at December 31, 2025 and 2024, respectively	5	—
Additional paid-in capital	819,115	5,577
Accumulated other comprehensive (loss) income	(228)	163
Accumulated deficit	(360,520)	(199,368)
Total stockholders' equity (deficit)	458,372	(193,628)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	$ 479,512	$ 136,916

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

MapLight Therapeutics, Inc.
Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share amounts)

	Year Ended December 31,	
	2025	**2024**
Operating expenses:		
Research and development	$ 138,349	$ 68,523
General and administrative	30,734	14,423
Total operating expenses	169,083	82,946
Loss from operations	(169,083)	(82,946)
Other income (expense), net:		
Interest income	5,518	4,504
Loss from equity method investment	—	(986)
Other income, net	2,413	1,848
Total other income, net	7,931	5,366
Net loss	$ (161,152)	$ (77,580)
Net loss per share - basic and diluted	$ (18.56)	$ (105.38)
Weighted-average number of common shares outstanding - basic and diluted	8,680,741	736,178
Comprehensive loss:		
Net loss	(161,152)	(77,580)
Other comprehensive (loss) income:		
Unrealized (loss) gain on available-for-sale investments	(391)	163
Comprehensive loss	$ (161,543)	$ (77,417)

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

MapLight Therapeutics, Inc.
Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)
(in thousands, except share amounts)

	Series D Redeemable Convertible Preferred		Series C Redeemable Convertible Preferred		Series B-1 Redeemable Convertible Preferred		Series B Redeemable Convertible Preferred		Series A-1 Redeemable Convertible Preferred		Series A Redeemable Convertible Preferred		Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Capital	(Loss) Income	Deficit	Equity (Deficit)
Balance, December 31, 2023	—	$—	68,751,919	$105,036	4,622,496	$11,981	45,010,383	$51,094	14,946,844	$15,963	5,000,000	$4,793	667,305	$—	$4,203	$—	$(121,788)	$(117,585)
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	—	—	—	—	1,080	—	—	1,080
Issuance of Series C redeemable convertible preferred stock, net of issuance costs of $44	—	—	78,573,608	119,956	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Issuance of common stock from exercises of stock options	—	—	—	—	—	—	—	—	—	—	—	—	93,971	—	294	—	—	294
Unrealized gain on available-for-sale investments	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	163	—	163
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(77,580)	(77,580)
Balance, December 31, 2024	—	$—	147,325,527	$224,992	4,622,496	$11,981	45,010,383	$51,094	14,946,844	$15,963	5,000,000	$4,793	761,276	$—	$5,577	$163	$(199,368)	$(193,628)
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	—	—	—	—	36,006	—	—	36,006
Issuance of Series D redeemable convertible preferred stock, net of issuance costs of $1,160	210,033,285	198,840	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Conversion of redeemable convertible preferred stock into common stock upon closing of initial public offering	(210,033,285)	(198,840)	(147,325,527)	(224,992)	(4,622,496)	(11,981)	(45,010,383)	(51,094)	(14,946,844)	(15,963)	(5,000,000)	(4,793)	25,412,974	3	507,660	—	—	507,663
Issuance of common stock upon closing of initial public offering and private placement, net of offering costs and underwriting fees of $27,374	—	—	—	—	—	—	—	—	—	—	—	—	17,439,207	2	269,091	—	—	269,093
Issuance of common stock from exercises of stock options	—	—	—	—	—	—	—	—	—	—	—	—	42,498	—	285	—	—	285
Issuance of common stock to NeuroSolis, Inc.	—	—	—	—	—	—	—	—	—	—	—	—	26,607	—	496	—	—	496
Settlement of restricted stock units	—	—	—	—	—	—	—	—	—	—	—	—	341,526	—	—	—	—	—
Unrealized loss on available-for-sale investments	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(391)	—	(391)
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(161,152)	(161,152)
Balance, December 31, 2025	—	$—	—	$—	—	$—	—	$—	—	$—	—	$—	44,024,088	$5	$819,115	$(228)	$(360,520)	$458,372

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

MapLight Therapeutics, Inc.
Consolidated Statements of Cash Flows
(in thousands)

	Year Ended December 31,	
	2025	**2024**
Cash flows from operating activities		
Net loss	$ (161,152)	$ (77,580)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	578	701
Stock-based compensation expense	36,006	1,080
Net amortization of premiums and accretion of discounts on investments	(2,102)	(1,741)
Common stock issued to NeuroSolis, Inc.	496	—
Non-cash lease expense	866	745
Loss from equity method investment	—	986
Loss on disposal of property and equipment	7	59
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(13,103)	(2,277)
Accounts payable	1,384	(1,345)
Accrued expenses	2,899	2,169
Operating lease liabilities	(777)	(653)
Deferred grant earnings	(3,239)	(959)
Net cash used in operating activities	(138,137)	(78,815)
Cash flows from investing activities		
Purchases of short-term and long-term investments	(408,234)	(125,018)
Maturities of marketable debt securities	85,500	45,000
Purchases of property and equipment	(473)	(770)
Net cash used in investing activities	(323,207)	(80,788)
Cash flows from financing activities		
Payments of deferred offering costs	(5,021)	(2,190)
Proceeds from issuance of Series C redeemable convertible preferred stock and preferred stock purchase right, net of issuance costs	—	119,956
Proceeds from issuance of Series D redeemable convertible preferred stock, net of issuance costs	198,840	—
Proceeds from initial public offering of common stock and private placement, net of underwriting fees	275,716	—
Proceeds from exercises of stock options	285	294
Net cash provided by financing activities	469,820	118,060
Increase (decrease) in cash, cash equivalents, and restricted cash	8,476	(41,543)
Cash, cash equivalents, and restricted cash at beginning of period	38,460	80,003
Cash, cash equivalents, and restricted cash at end of period	$ 46,936	$ 38,460
Supplemental disclosure of non-cash investing and financing activities:		
Conversion of redeemable convertible preferred stock into common stock on closing of initial public offering	$ 507,663	$ —
Right-of-use asset obtained in exchange for operating lease liability	$ —	$ 1,485
Purchase of property and equipment included in accounts payable and accrued expenses	$ —	$ 226
Deferred financing costs included in accounts payable and accrued expenses	$ —	$ 848

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

1. Nature of the Business

MapLight Therapeutics, Inc. ("MapLight" or the "Company") was incorporated in November 2018 as Alvarado Therapeutics, Inc., a Delaware corporation. In August 2019, the Company changed its name to MapLight Therapeutics, Inc. The Company is a clinical-stage biopharmaceutical company focused on improving the lives of patients suffering from debilitating central nervous system ("CNS") disorders.

Risks and Uncertainties

The Company is subject to risks and uncertainties common to clinical-stage companies in the biotechnology industry, including, but not limited to, completing preclinical studies and clinical trials, obtaining regulatory approval for its programs, market acceptance of products, developments related to its competitors, dependence on key personnel, the ability to attract and retain qualified employees, reliance on third-party organizations, protection of intellectual property, compliance with government regulations and the ability to secure additional capital to fund operations. Product candidates currently under development will require significant additional research and development efforts, including preclinical and clinical testing and regulatory approval, prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel and infrastructure and extensive compliance-reporting capabilities. Even if the Company's product development efforts are successful, it is uncertain when, if ever, the Company will realize revenue from product sales.

Reverse Stock Split, Initial Public Offering and Concurrent Private Placement

In October 2025, the Company's Board of Directors (the "Board") approved a 1-for-16.8 reverse stock split of the Company's common stock. This also resulted in an adjustment to the conversion price for each series of the Company's redeemable convertible preferred stock, to the number of shares of common stock underlying outstanding restricted stock units, and to the exercise prices and number of shares of common stock underlying outstanding stock options. Accordingly, all share and per share information relating to common stock for all periods presented in the accompanying consolidated financial statements and notes thereto have been retroactively adjusted. The per share par value and authorized number of shares of the Company's common stock were not adjusted as a result of the reverse stock split.

In October 2025, the Company closed its initial public offering ("IPO"), pursuant to which the Company issued and sold an aggregate of 16,962,500 shares of its common stock at a public offering price of $17.00 per share for gross proceeds of $288.4 million. The Company received aggregate net proceeds of $261.6 million from the IPO, including the exercise by the underwriters of their option to purchase additional shares, after deducting underwriting discounts and commissions and offering expenses. Concurrent with the IPO, the Company also closed a private placement, in which the Company issued and sold 476,707 shares of its common stock at a price of $17.00 per share (the "Concurrent Private Placement"). The Company received aggregate net proceeds of $7.5 million from the Concurrent Private Placement, after deducting placement agent fees and private placement expenses.

Upon the closing of the IPO, all of the Company's then-outstanding shares of redeemable convertible preferred stock converted into 25,412,974 shares of common stock (of which 2,727,511 shares were non-voting common stock) at the applicable conversion ratio then in effect. Subsequent to the closing of the IPO, there were no shares of redeemable convertible preferred stock outstanding.

Liquidity and Going Concern

The Company's consolidated financial statements have been prepared on the basis of continuity of operations, realization of assets and the satisfaction of liabilities in the ordinary course of business. The Company has experienced negative operating cash flows since inception, and had an accumulated deficit of $360.5 million as of December 31, 2025. The Company expects to continue to generate operating losses for the foreseeable future. The Company's future viability is dependent on its ability to raise additional capital to finance its operations and pursue

its business strategies. There can be no assurances that additional funding will be available on terms acceptable to the Company, or at all.

The Company has funded its operations primarily with proceeds from the sale of capital stock and research and development grants received. The Company's current plans include funding multiple clinical trials, including Phase 2 trials for its lead product candidate, ML-007C-MA, and ML-004, as well as continued advancement of its current and future preclinical programs. Based on its current operating plans and financial position, the Company believes that its existing cash, cash equivalents and investments of $453.1 million will be sufficient to allow the Company to fund its operations for at least twelve months from the date these consolidated financial statements were issued.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements have been prepared in accordance with accounting standards set by the Financial Accounting Standards Board ("FASB"). The FASB sets generally accepted accounting principles ("GAAP") to ensure the consolidated financial statements are consistently reported. References to GAAP issued by the FASB in these footnotes are to the FASB Accounting Standards Codification ("ASC").

The consolidated financial statements include those of MapLight and the Company's wholly owned subsidiary, MapLight Australia Pty. Ltd. ("MapLight AUS"). MapLight AUS was established in August 2021. All intercompany accounts and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of the Company's consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, expenses and the related disclosures at the date of the consolidated financial statements and reported amounts of expenses during the reporting period. On an ongoing basis, the Company evaluates its estimates, which include but are not limited to judgments of research and development accruals and expenses, fair value of common stock, valuation of share-based awards and income taxes. Actual results could differ from those estimates.

Segment Information

The Company has one reportable segment focused on the research and development of therapies for CNS disorders and manages its operations on a consolidated basis for the purpose of allocating resources. The Company's chief operating decision maker is its chief executive officer, who reviews financial information presented on a consolidated basis for purposes of making operating decisions, assessing financial performance, and allocating resources. As of December 31, 2025 and 2024, all of the Company's long-lived assets are held in the United States.

Foreign Currency

A subsidiary's functional currency is the currency of the primary economic environment in which the subsidiary operates; normally, that is the currency of the environment in which a subsidiary primarily generates and expends cash. In making the determination of the appropriate functional currency for a subsidiary, the Company considers cash flow indicators, local market indicators, financing indicators and the subsidiary's relationship with both the parent company and other subsidiaries.

The functional currency of the Company's wholly owned Australian entity is the U.S. dollar. All foreign currency transaction gains and losses are recognized in the consolidated statements of operations and comprehensive loss through other income, net. The Company did not recognize any material foreign currency transaction gain or loss during the years ended December 31, 2025 and 2024.

Cash and Cash Equivalents

The Company considers all highly liquid investments purchased with an original maturity of 90 days or less at acquisition to be cash equivalents which are stated at fair market value. Cash equivalents for the years ended December 31, 2025 and 2024 consists of cash held in overnight sweep accounts and money market funds.

Restricted Cash

Cash accounts with any type of restriction are classified as restricted cash. The Company has restricted cash deposits with a bank, which serve as collateral for a letter of credit issued to the landlord of the Company's leased facility for a security deposit (Note 7) and as collateral to the Company's corporate credit card program. As of December 31, 2025 and 2024, restricted cash was $0.2 million.

Deferred Financing Costs

The Company capitalizes certain legal, professional accounting and other third-party fees that are directly associated with in-process equity financings as deferred financing costs until such financings are consummated. After consummation of an equity financing, these costs are recorded as a reduction of the proceeds from the financing, either as a reduction of the carrying value of the preferred stock or in stockholders' deficit as a reduction of additional paid-in capital generated as a result of the offering. If an in-process equity financing were abandoned, the deferred offering costs would be expensed immediately as a charge to operating expenses in the consolidated statements of operations and comprehensive loss.

Upon closing the IPO in October 2025, the related deferred offering costs were recorded against the IPO proceeds. No deferred offering costs were recorded as of December 31, 2025. As of December 31, 2024, the Company had $3.0 million in deferred offering costs which were included in other assets on the Company's consolidated balance sheet.

Concentration of Credit Risk and Off-Balance Sheet Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash, cash equivalents and investments. The Company maintains its cash, cash equivalents and investments, which at times exceed insurance limits, at major financial institutions. The Company has not experienced any credit losses in such accounts and management believes that such funds are not exposed to any significant credit or concentration risk. However, the Company may face exposure, including constraint on liquidity and access to capital, if there is failure by these or other financial institutions.

The Company has no off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on the Company's financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources.

Comprehensive Loss

Comprehensive loss includes net loss and certain changes in stockholders' equity that are excluded from net loss resulting from transactions from non-owner sources. The Company had a net change in available-for-sale securities during the years ended December 31, 2025 and 2024, which met the criteria for inclusion in other comprehensive loss and, therefore, the Company's comprehensive loss includes net unrealized gains and losses on those available-for-sale securities.

Investments

The Company's investments consist of marketable debt securities. Marketable debt securities with contractual maturities less than 12 months at the balance sheet date are considered short-term marketable securities. Marketable debt securities with contractual maturities 12 months or greater at the balance sheet date are considered long-term marketable securities. The Company classifies all investments held as available-for-sale. Available-for-sale

securities are recorded at fair value based upon market prices at period end, with the unrealized gains and losses reported in other comprehensive loss. The amortized cost of debt securities in this category is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization is included in other income, net in the consolidated statements of operations and comprehensive loss. Realized gains and losses and declines in value due to credit-related factors on available-for-sale securities are included in other income, net in the consolidated statements of operations and comprehensive loss. The cost of securities sold is based on the specific identification method. Interest on securities classified as available-for-sale is included in interest income in the consolidated statements of operations and comprehensive loss.

At each balance sheet date, the Company assesses available-for-sale debt securities in an unrealized loss position to determine whether the unrealized loss or any potential credit losses should be recognized in other income, net. The Company evaluates whether it intends to sell, or it is more likely than not that it will be required to sell, the security before recovery of its amortized cost basis. The Company also evaluates whether the decline in fair value has resulted from credit losses or other factors. In making this assessment, the Company considers the severity of the impairment, any changes in interest rates, changes to the underlying credit ratings and forecasted recovery, among other factors. The credit-related portion of unrealized losses, and any subsequent improvements, are recorded in other income, net. There have been no impairment or credit losses recognized during any of the periods presented.

Fair Value Measurements

ASC Topic 820, *Fair Value Measurement* ("ASC 820"), establishes a fair value hierarchy for instruments measured at fair value that distinguishes between assumptions based on market data (observable inputs) and the Company's own assumptions (unobservable inputs). Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the inputs that market participants would use in pricing the asset or liability and are developed based on the best information available in the circumstances.

ASC 820 identifies fair value as the exchange price, or exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As a basis for considering market participant assumptions in fair value measurements, ASC 820 establishes a three-tier fair value hierarchy that distinguishes among the following:

Level 1—Quoted prices in active markets for identical assets or liabilities.

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 that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

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 requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement. Fair value information for assets recorded at fair value by the Company, including their classification in the fair value hierarchy, is included in Note 4.

Property and Equipment, Net

Property and equipment are stated at cost, less accumulated depreciation. Costs of major additions and betterments are capitalized. Maintenance and repairs that do not improve or extend the life of the respective assets are expensed as incurred. Depreciation is calculated using the straight-line method over the estimated useful lives of

the assets, which range from three to five years. Leasehold improvements are amortized over the shorter of fifteen years or the lease term of the related asset. When an item is sold or retired, the costs and related accumulated depreciation are eliminated, and the resulting gain or loss, if any, is recorded in the consolidated statement of operations and comprehensive loss. Property and equipment to be disposed of are carried at fair value less costs to sell. The estimated useful lives of the Company's property and equipment are as follows:

	Estimated Useful Life (in Years)
Laboratory equipment, computer equipment, and clinical equipment	3 years
Furniture	5 years
Leasehold improvements	Lesser of 15 years or lease term

Impairment of Long-Lived Assets

The Company continually evaluates long-lived assets for potential impairment when events or changes in circumstances indicate the carrying value of the assets may not be recoverable. Recoverability is measured by comparing the carrying value of the asset group to the expected future net undiscounted cash flows that the asset group is expected to generate. If an asset group is considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying value of the asset group exceeds its fair value. The Company did not recognize any impairment losses for years ended December 31, 2025 and 2024.

Asset Acquisitions and Acquired In-Process Research and Development Expenses

The Company accounts for acquisitions of assets or a group of assets that do not meet the definition of a business as asset acquisitions based on the cost to acquire the asset or group of assets, which includes certain transaction costs. In an asset acquisition, the cost to acquire is allocated to the identifiable assets acquired and liabilities assumed based on their relative fair values as of the acquisition date. No goodwill is recorded in an asset acquisition. Assets that are acquired in an asset acquisition for use in research and development activities that have an alternative future use are capitalized as in-process research and development ("IPR&D"). Acquired IPR&D that has no alternative future use as of the acquisition date is recognized as research and development expense as of the acquisition date. The Company will recognize additional research and development expenses in the future if and when the Company becomes obligated to make contingent milestone payments under the terms of the agreements by which it acquired the IPR&D assets.

Contingent consideration in asset acquisitions is measured and recognized when the contingencies are resolved and the consideration is paid or becomes payable. Subsequent changes in the accrued amount of contingent consideration are measured and recognized at the end of each reporting period and upon settlement as an adjustment to the cost basis of the acquired asset or group of assets, or, if related to IPR&D with no alternative future use, charged to expense.

Leases

At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease. A contract is or contains a lease if the contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration. At the lease commencement date, when control of the underlying asset is transferred from the lessor to the lessee, the Company classifies leases as operating or finance leases and recognizes a right-of-use ("ROU") asset and current and noncurrent lease liabilities, as applicable, on the consolidated balance sheet for all leases with a term greater than one year. The Company made an accounting policy election, known as the short-term lease recognition exemption, which allows the Company to not recognize ROU assets and lease liabilities that arise from leases with a term of twelve months or less for all classes of underlying assets. The Company only includes the committed lease term in the assessment of lease arrangements. Options to renew or options to cancel a lease are not included in the assessment unless there is reasonable certainty that the Company will renew or will not cancel, respectively.

Operating lease liabilities and their corresponding ROU assets are recorded at the lease commencement date based on the present value of future lease payments over the expected remaining lease term using the discount rate

implicit in the lease, if readily determinable. The interest rate implicit in lease contracts is typically not readily determinable. As a result, the Company utilized the incremental borrowing rate, the rate of interest that the Company would have to pay to borrow on a collateralized basis over a similar term in an amount equal to the lease payments in a similar economic environment. The determined incremental borrowing rate is based on general credit, with adjustments subsequently made to reflect the impact on collateral to the incremental borrowing rate.

The Company may enter into contracts that contain both lease and non-lease components. Non-lease components include costs that do not provide a right-to-use a leased asset but instead provide a service, such as maintenance costs. The Company elected to combine the lease and non-lease components together as a single lease component for all existing classes of underlying assets. Variable costs associated with the lease, such as maintenance and utilities, are not included in the measurement of right-to-use assets and lease liabilities but rather are expensed when the events determining the amount of variable consideration to be paid have occurred.

In addition, the Company examines other contracts with suppliers, vendors and outside parties to identify whether such contracts contain an embedded lease and, as applicable, records such embedded leases in accordance with ASC 842.

Research and Development Expense and Accruals

In preparing the consolidated financial statements, the Company estimates amounts related to accrued research and development expenses. This process involves reviewing open contracts and purchase orders, communicating with personnel and contract research organizations ("CROs") to identify services that have been performed on the Company's behalf and estimating the level of service performed and the associated costs incurred for the services when the Company has not yet been invoiced or otherwise notified of the actual costs. The majority of research and development service providers invoice in arrears for services performed, on a predetermined schedule or when contractual milestones are met; however, some require advance payments. The Company makes estimates of accrued expenses as of each consolidated balance sheet date in the consolidated financial statements based on facts and circumstances known to at that time. Examples of estimated accrued research and development expenses include fees paid to:

- CROs in connection with performing research services and clinical trials on the Company's behalf;
- investigators, clinical sites or other providers in connection with clinical trials;
- vendors in connection with preclinical and clinical development activities; and
- vendors related to product manufacturing, development and distribution of preclinical and clinical material and supplies.

Expenses relate to preclinical studies and clinical trials based on estimates of the services received and efforts expended pursuant to quotes and contracts with multiple CROs that conduct and manage clinical trials on behalf of the Company. 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 vendors will exceed the level of services provided and result in a prepayment of the preclinical and clinical expenses. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing service fees, the Company estimates the time period over which services will be performed, enrollment of patients, number of sites activated and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, the Company adjusts the accrual or amount of prepaid expense accordingly. Although the Company does not expect the estimates to be materially different from amounts actually incurred, the understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in the Company reporting amounts that are too high or too low in any particular period. To date, the Company has not made any material adjustments to prior estimates of accrued research and development expenses.

Patent Costs

All patent-related costs incurred in connection with filing and prosecuting patent applications such as direct application fees, and legal and consulting expenses are expensed as incurred due to the uncertainty about the recovery of the expenditure. Patent-related costs are classified as general and administrative expenses within the Company's consolidated statements of operations.

Grant Earnings

The Company assesses contracts received, including cost reimbursement agreements, to determine if the agreement should be accounted for as an exchange transaction or a grant. An agreement is accounted for as a grant if the resource provider does not receive commensurate value in return for the assets transferred. The Company accounts for contracts in which the resource provider is not receiving commensurate value as a grant through analogy to International Accounting Standards 20 ("IAS 20"), *Accounting for Government Grants and Disclosure of Government Assistance*.

Funds to be received under a grant are accounted for according to the nature of the reimbursable item. Funds received for the purchase of property and equipment are accounted for as a reduction to the carrying value of the corresponding asset. Funds received for the reimbursement of expenses incurred related to research and development are accounted for as a reduction of the associated expense. Grant earnings are recognized as the related reimbursable expenses are incurred and both of the following conditions are met: (1) the Company is able to comply with the relevant conditions of the grant and (2) the grant will be received. See Note 17 of the consolidated financial statements for further discussion on grants.

Stock-Based Compensation

The Company accounts for stock-based compensation in accordance with ASC 718, *Compensation—Stock Compensation* ("ASC 718"). ASC 718 requires all share-based payments to employees and directors to be recognized as expense in the consolidated statement of operations and comprehensive loss based on their grant date fair values. The Company estimates the fair value of options granted using the Black-Scholes option pricing model for stock option grants to both employees and non-employees. The Company believes the fair value of the stock options granted to non-employees is more reliably determinable than the fair value of the services provided.

The Black-Scholes option pricing model requires inputs based on certain subjective assumptions, including (a) the stock price, (b) the expected volatility, (c) the expected term of the award, (d) the risk-free interest rate and (e) expected dividends. Prior to the IPO, the Board determined the fair value of the Company's common stock, taking into consideration its most recently available third-party valuations of common stock as well as additional factors that may have changed since the date of the most recent contemporaneous valuation through the grant date. Prior to the IPO, the Company was a private company that lacked company-specific historical and implied volatility information. Following the IPO, the fair value of the Company's common stock is determined based on the quoted market price of common stock. The historical volatility is calculated based on a period of time commensurate with the expected term assumption. The Company uses the simplified method as prescribed by the U.S. Securities and Exchange Commission ("SEC") Staff Accounting Bulletin No. 107, Share-Based Payment, to calculate the expected term for options granted to employees as the Company does not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term. The expected term is applied to the stock option grant group as a whole, as the Company does not expect substantially different exercise or post-vesting termination behavior among the Company's employee population. For options granted to non-employees, the Company utilizes the contractual term of the share-based payment as the basis for the expected term assumption. The risk-free interest rate is based on a treasury instrument whose term is consistent with the expected term of the stock options. The expected dividend yield is assumed to be zero as the Company has never paid dividends and has no current plans to pay any dividends on common stock.

There are significant judgments and estimates inherent in the determination of the fair value of common stock. These estimates and assumptions include a number of objective and subjective factors, including external market conditions and the prices at which the Company sold shares of redeemable convertible preferred stock.

The Company expenses the fair value of share-based compensation awards to employees and non-employees that have time-based vesting criteria on a straight-line basis over the requisite service period, which is generally the vesting period. Forfeitures are recognized as they occur. The Company expenses the fair value of share-based compensation awards to employees and non-employees that have performance-based vesting criteria when the performance condition is considered probable of achievement, using management's best estimates, which consider the inherent risk and uncertainty regarding the future outcomes of the milestones.

Redeemable Convertible Preferred Stock

Preferred securities that were redeemable for cash or other assets were classified outside of permanent equity if they were redeemable (1) at a fixed or determinable price on a fixed or determinable date, (2) at the option of the holder, or (3) upon the occurrence of an event that is not solely within the issuer's control. The Company classified redeemable convertible preferred stock in mezzanine equity, or temporary equity, as the redeemable convertible preferred stock was contingently redeemable upon the occurrence of an event that is outside of the Company's control. After the closing of the IPO, all of the Company's outstanding shares of redeemable convertible preferred stock converted into shares of common stock.

Income Taxes

The Company accounts for income taxes using the asset and liability method in accordance with ASC Topic 740, Income Taxes ("ASC 740") which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the consolidated financial statements or in the tax returns. Deferred tax assets and liabilities are determined on the basis of the differences between the financial statement and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes. The Company assesses the likelihood that deferred tax assets will be recovered from future taxable income and, to the extent the Company believes, based upon the weight of available evidence, that it is more likely than not that all or a portion of the deferred tax assets will not be realized, a valuation allowance is established through a charge to income tax expense. Potential for recovery of deferred tax assets is evaluated by estimating the future taxable profits expected and considering prudent and feasible tax planning strategies. At December 31, 2025 and 2024, the Company concluded that a full valuation allowance is necessary for deferred tax assets (Note 13).

Equity Method of Accounting

In circumstances where the Company has the ability to exercise significant influence, but not control, over the operating and financial policies of an entity in which the Company has an investment in common stock or in-substance common stock, the Company utilizes the equity method of accounting for recording related investment activity. In assessing whether it exercises significant influence, the Company considers the nature and magnitude of the investment, participating rights the Company holds, and relevant factors such as representation on the board of directors.

Under the equity method of accounting, the Company's investments are initially recorded at cost on the consolidated balance sheets. Upon recording an equity method investment, the Company evaluates whether there are basis differences between the carrying value and fair value of the Company's proportionate share of the investee's underlying net assets. Typically, the Company amortizes basis differences identified on a straight-line basis over the underlying asset's or liability's estimated useful life when calculating the attributable earnings or losses. If the Company is unable to attribute all of the basis difference to specific assets or liabilities of the investee, the residual excess of the cost of the investment over the proportional fair value of the investee's assets and liabilities is considered to be equity method goodwill and is recognized within the equity investment balance. The Company subsequently records in the consolidated statements of operations its share of income or loss of the other entity within the loss from equity method investment line item. If the share of losses exceeds the carrying value of the Company's investment, the Company will suspend recognizing additional losses and will continue to do so unless it commits to providing additional funding or commits to guarantee investee liabilities.

The Company evaluates its equity method investments for impairment whenever events or changes in circumstances indicate that the carrying amounts of such investments may be impaired and considers qualitative and

quantitative factors including the investee's financial metrics, product and commercial outlook and cash usage. If a decline in the value of an equity method investment is determined to be other than temporary, a loss is recorded in earnings in the current period and the investment is written down to fair value.

At December 31, 2025 and 2024, the Company accounted for its investment in Stellaromics under the equity method of accounting. Refer to Note 8 of the consolidated financial statements for further details.

Recently Adopted Accounting Pronouncements

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740)—Improvements to Income Tax Disclosures*. ASU 2023-09 is intended to improve income tax disclosure requirements by requiring (1) consistent categories and greater disaggregation of information in the rate reconciliation and (2) the disaggregation of income taxes paid by jurisdiction. The guidance makes several other changes to the income tax disclosure requirements as well. ASU 2023-09 is effective for annual periods beginning after December 15, 2024 and allows for adoption on a prospective basis, with a retrospective option. The Company adopted this accounting standard on a prospective basis effective for its annual period ending December 31, 2025. Refer to Note 13 for further details.

Recently Issued But Not Yet Adopted Accounting Pronouncements

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 entities to disclose additional information about specific expense categories in the notes to the financial statements. The update is effective for annual periods beginning after December 15, 2026 and for interim periods within fiscal years beginning after December 15, 2027. Early adoption is permitted. ASU 2024-03 may be applied retrospectively or prospectively. The Company is currently evaluating the effect of this update on its consolidated financial statements and related disclosures.

3. Investments

The following tables summarize the amortized cost and estimated fair value of the Company's U.S. Treasury securities, U.S. government agency bonds, commercial paper and corporate debt securities, which are considered to be available-for-sale investments and were included in short-term investments and long-term investments as of December 31, 2025 and 2024 (in thousands):

	December 31, 2025			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Short-term investments:				
U.S. Treasury securities	$ 95,550	$ 72	$ (13)	$ 95,609
Commercial paper	137,101	22	(19)	137,104
Corporate debt securities	25,680	18	(37)	25,661
Long-term investments:				
U.S. Treasury securities	73,072	—	(60)	73,012
Corporate debt securities	75,192	—	(211)	74,981
	$ 406,595	$ 112	$ (340)	$ 406,367

	December 31, 2024			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Short-term investments:				
U.S. Treasury securities	$ 53,600	$ 78	$ (2)	$ 53,676
U.S. government agency bonds	4,988	8	—	4,996
Corporate debt securities	11,837	33	—	11,870
Long-term investments:				
Corporate debt securities	11,334	46	—	11,380
	$ 81,759	$ 165	$ (2)	$ 81,922

Certain short-term debt securities with original maturities of less than 90 days are included in cash and cash equivalents on the consolidated balance sheets and are not included in the tables above. As of December 31, 2025, all short-term investments had contractual maturities within one year.

The aggregate fair value of available-for-sale securities held by the Company in an unrealized loss position for less than 12 months as of December 31, 2025 was $242.7 million. The unrealized loss associated with available for-sale securities was approximately $0.3 million. There were no available-for-sale securities in a continuous unrealized loss position for greater than 12 months. The Company evaluated its securities for potential impairment and considered the decline in market value to be primarily attributable to current economic and market conditions. Additionally, the Company does not intend to sell the investments in an unrealized loss position and does not expect it will be required to sell the investments before recovery of their amortized cost bases, which may be at the time of maturity. Given the Company's intent and ability to hold such investments until the recovery of their amortized cost basis, and the lack of a significant change in credit risk for these investments, the Company does not consider these investments to be impaired and there were no allowances for credit losses as of December 31, 2025 and 2024.

4. Fair Value Measurement

The following table presents information about the Company's financial assets measured at fair value on a recurring basis (in thousands):

		Fair Value Measurements at December 31, 2025 Using:		
	Total	Level 1	Level 2	Level 3
Assets:				
Cash equivalents:				
Money market funds	$ 30,833	$ 30,833	$ —	$ —
Short-term investments:				
U.S. Treasury securities	95,609	95,609	—	—
Commercial paper	137,104	—	137,104	—
Corporate debt securities	25,661	—	25,661	—
Long-term investments:				
U.S. Treasury securities	73,012	73,012	—	—
Corporate debt securities	74,981	—	74,981	—
Total assets	$ 437,200	$ 199,454	$ 237,746	$ —

	Total	Fair Value Measurements at December 31, 2024 Using: Level 1	Level 2	Level 3
Assets:				
Cash equivalents:				
Money market funds	$ 20,607	$ 20,607	$ —	$ —
Short-term investments:				
U.S. Treasury securities	53,676	53,676	—	—
U.S. government agency bonds	4,996	—	4,996	—
Corporate debt securities	11,870	—	11,870	—
Long-term investments:				
Corporate debt securities	11,380	—	11,380	—
Total assets	$ 102,529	$ 74,283	$ 28,246	$ —

The Company classifies its money market funds and U.S. Treasury securities as Level 1 assets under the fair value hierarchy as these assets have been valued using quoted market prices in active markets without any valuation adjustment. The Company classifies its U.S. government agency bonds, commercial paper and corporate debt securities as Level 2 assets under the fair value hierarchy as these assets have been valued using information obtained through a third-party pricing service as of the balance sheet date, using observable market inputs that may include trade information, broker or dealer quotes, bids, offers, or a combination of these data sources.

During the years ended December 31, 2025 and 2024, there were no transfers between levels. The Company uses the carrying amounts of its restricted cash, prepaid expenses and other current assets, accounts payable, and accrued expenses and other current liabilities to approximate their fair values due to the short-term nature of these amounts.

5. Property and Equipment, Net

Property and equipment, net, consisted of the following (in thousands):

	December 31, 2025	2024
Lab equipment	$ 2,549	$ 2,104
Computer equipment	627	627
Clinical equipment	517	517
Other property and equipment	41	41
Total property and equipment	3,734	3,289
Less: accumulated depreciation	(2,639)	(2,082)
Property and equipment, net	$ 1,095	$ 1,207

Depreciation expense related to property and equipment for the years ended December 31, 2025 and 2024 was $0.6 million and $0.7 million, respectively.

6. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	December 31,	
	2025	2024
Employee compensation	$ 6,162	$ 4,013
Research and development	4,829	4,313
Legal services	537	107
Other	521	1,558
Total accrued expenses	$ 12,049	$ 9,991

7. Leases

The Company leases office and laboratory space which are classified as operating leases on the consolidated balance sheets.

In August 2020, the Company entered into a lease agreement for 10,500 square feet of office and lab space in Redwood City, California. In May 2021, the Company entered into the first amendment to extend the term to expire the last day of the twenty-sixth month after commencement. The lease commenced in June 2021. In August 2022, the Company entered into a second amendment to the lease, increasing the office and lab space to 11,655 square feet effective in August 2022 and to 13,734 square feet effective in August 2023. Additionally, the term of the lease was extended to June 2031. The Company and the lessor have the ability to terminate the lease with 15 months' notice. Upon execution of the second amendment, the right-of-use asset and lease liability balances were $6.3 million and $6.4 million, respectively. Cash required to be held as a security deposit in accordance with the lease is $0.2 million.

In September 2023, the Company entered into a lease agreement for office space in Burlington, Massachusetts. This lease commenced in April 2024, when the Company took occupancy of the space for its intended use, and has an initial term of approximately five years, with an option to extend the term for an additional five years. At lease commencement, the Company recognized a right-of-use asset and lease liability of $1.5 million and $1.3 million, respectively. Cash required to be held as a security deposit in accordance with the lease is $0.2 million.

The following table summarizes the presentation of the Company's operating leases on its consolidated balance sheets (in thousands):

Leases	Balance Sheet Classification	2025	2024
Assets:			
Operating lease assets	Right-of-use asset	$ 5,488	$ 6,354
Total lease assets		$ 5,488	$ 6,354
Liabilities:			
Current:			
Operating lease liabilities	Lease liability - current	$ 891	$ 778
Noncurrent:			
Operating lease liabilities	Lease liability - non-current	4,911	5,801
Total lease liabilities		$ 5,802	$ 6,579

The components of lease cost under ASC Topic 842, *Leases* included within research and development expenses and general and administrative expenses in the Company's consolidated statements of operations and comprehensive loss were as follows (in thousands):

	Year Ended December 31,	
Lease Cost	**2025**	**2024**
Operating lease costs	$ 1,383	$ 1,292
Variable lease costs	290	264
Total lease cost	$ 1,673	$ 1,556

As of December 31, 2025 and 2024, the weighted-average remaining lease term for operating leases was 5.2 years and 6.2 years, respectively, and the weighted-average discount rate was 8.7% and 8.8%, respectively. Cash paid for amounts included in the measurement of lease liabilities was $1.3 million for the year ended December 31, 2025.

Future minimum annual lease commitments under the Company's non-cancelable operating leases as of December 31, 2025 were as follows (in thousands):

Year Ended December 31,	**Amount**
2026	$ 1,335
2027	1,376
2028	1,419
2029	1,263
2030	1,163
Thereafter	590
Total lease payments	7,146
Less: imputed interest	(1,344)
Present value of operating lease liabilities	$ 5,802

8. Equity Method Investment

In October 2023, the Company entered into an Assignment and Assumption Agreement (the "Stellaromics Agreement") with Stellaromics, Inc. ("Stellaromics"), an entity focused on developing and commercializing a proprietary three-dimensional transcriptomic device inclusive of a confocal, probes, operating software and sample analysis software, pursuant to which in exchange for contributing an exclusive worldwide license for STARmap, a three-dimensional intact tissue sequencing, imaging and analysis technology, the Company received 9.8% of the capital stock of Stellaromics at the time of the closing. As of December 31, 2025, the Company held approximately 20.6% of the outstanding common stock of Stellaromics and approximately 3.7% of all classes of outstanding stock. Additionally, the Company's current Chief Executive Officer is a member of Stellaromics' board of directors. The Company does not have contractual rights to nominate any members to the Stellaromics board of directors.

The Company has significant influence over, but does not control, Stellaromics through its noncontrolling representation on Stellaromics' board of directors and the Company's equity interest in Stellaromics. The Company determined that Stellaromics is a variable interest entity because it does not have sufficient equity at risk to finance its operations without additional subordinated financial support. The Company is not the primary beneficiary as it does not have the power to direct activities that most significantly impact Stellaromics' economic performance. Accordingly, the Company does not consolidate the financial statements of Stellaromics and accounts for its investment using the equity method of accounting. The determination of whether an entity is a variable interest entity and whether the Company is the primary beneficiary of a variable interest entity is based upon the facts and circumstances and requires significant judgments such as whether the entity is a variable interest entity and whether

the Company is the primary beneficiary of the entity either individually or via a related party group. The Company's maximum exposure to loss due to its involvement with Stellaromics is the carrying value of the investment.

Upon the closing of the Stellaromics Agreement, the fair value of the Company's investment in Stellaromics was $1.1 million, which represented the fair value of the common stock received under the Stellaromics Agreement. The fair value of the Stellaromics common stock was determined by management. In determining the fair value of the Company's investment, the Company used an option pricing model/backsolve approach based on Stellaromics' most recent funding of preferred stock. The valuation required the input of certain subjective assumptions. The key assumptions used in the option pricing model, which are Level 3 inputs, included the anticipated holding period prior to an exit and liquidity event, the volatility of market participants and the discount for lack of marketability. The Company adjusts the carrying value of its investment in Stellaromics by its proportionate share of Stellaromics' net loss based on the Company's share of Stellaromics' outstanding common stock and in-substance common stock.

Upon the closing of the Stellaromics Agreement, a basis difference was identified as the carrying value of the Company's investment in Stellaromics exceeded the Company's proportionate share of the underlying net assets in Stellaromics. The Company concluded that the basis difference was primarily attributable to Stellaromics' in process research and development ("IPR&D") assets. As Stellaromics did meet the definition of a business, the basis difference attributable to the IPR&D with no alternative future use is tracked but not recorded until such time that the IPR&D asset is placed in service or impaired. For the years ended December 31, 2025 and 2024, the Company recognized a loss from its equity method investment of zero and $1.0 million, respectively, in the Company's consolidated statements of operations and comprehensive loss for its share of Stellaromics' loss after considering basis differences. As of December 31, 2025 and 2024, the carrying value of the investment was $0, and no further losses will be recorded because the Company does not have any obligation to fund future losses.

9. License Agreement

In November 2024, the Company entered into a license agreement with Vanderbilt University ("Vanderbilt") (the "Vanderbilt Agreement"), pursuant to which the Company has been granted an exclusive, royalty-bearing, worldwide sublicensable license to develop, make, have made, use, offer for sale, sell, import and exploit certain compounds and licensed products, and a non-exclusive, royalty-bearing, worldwide, sub-licensable license to use licensed know-how and tool compounds to develop, make, have made, use, offer for sale, sell, import and exploit certain compounds and licensed products.

As initial consideration for the license, the Company made a one-time, non-creditable, non-refundable upfront payment of $0.3 million upon the execution of the agreement. The Company also made a one-time, non-creditable, non-refundable payment of $0.3 million upon the execution of the agreement for the reimbursement of past patenting costs incurred by Vanderbilt. The total payment of $0.6 million is included in research and development expense in the consolidated statements of operations and comprehensive loss. As additional consideration for the license, the Company could be required to pay to Vanderbilt aggregate development and commercial milestone payments of up to $52.4 million. The Company is also required to pay royalties at a low single digit percentage based on annual net sales of licensed products sold by the Company. Such royalty payments are subject to reductions if sales are made in calendar quarters during which there is no valid claim or no market exclusivity for a licensed product. Any such royalties are payable on a country-by-country and licensed product-by-licensed product basis until the expiration of the last to expire valid claim of the licensed patents.

As of December 31, 2025, no milestone payments or royalties have been incurred related to the Vanderbilt Agreement.

10. Redeemable Convertible Preferred Stock

Prior to the IPO in October 2025, the Company had authorized 603,469,745 shares of voting redeemable convertible preferred stock, of which it had designated 5,000,000 shares as Series A Preferred Stock ("Series A"), 14,946,844 shares as Series A-1 Preferred Stock ("Series A-1"), 45,010,383 shares as Series B Preferred Stock ("Series B"), 147,325,527 shares as Series C Preferred Stock ("Series C") and 391,186,991 shares as Series D Preferred Stock ("Series D") (collectively, the "Voting Preferred Stock"), and had authorized 4,622,496 shares of

non-voting redeemable convertible preferred stock, of which it had designated 4,622,496 shares as Series B-1 Preferred Stock ("Series B-1") (collectively, the "Preferred Stock").

In connection with the IPO in October 2025, all outstanding shares of the Company's Preferred Stock automatically converted into an aggregate of 25,412,974 shares of the Company's common stock, of which 2,727,511 shares were non-voting common stock.

Issuances of Preferred Stock

On March 27, 2024, the Company issued a total of 78,573,608 shares of Series C at a purchase price of $1.52723 per share for gross proceeds of $120.0 million. The Company incurred issuance costs that were de minimis in connection with the issuance of Series C.

On July 18, 2025, the Company entered into a Series D Preferred Stock Purchase Agreement with certain investors (the "Series D Agreement"). During the year ended December 31, 2025, the Company issued a total of 210,033,285 shares of Series D to investors at a purchase price of $0.95223 per share for gross proceeds of $200.0 million. The Company incurred issuance costs of $1.2 million in connection with the issuances of Series D.

The Preferred Stock had the following rights and preferences prior to conversion into common stock upon the closing of the IPO:

Voting: Each holder of outstanding shares of Preferred Stock was entitled to cast the number of votes equal to the number of whole shares of common stock into which the shares of Preferred Stock held by such holder were convertible as of the record date for determining stockholders entitled to vote on such matter. The holders of outstanding shares of Series A, Series A-1 and Series B, voting together as a single class, were entitled to elect two members of the Board of Directors. The holders of outstanding shares of Series B and Series C, voting together as a single class, were entitled to elect two members of the Board of Directors. The holders of outstanding shares of Series C, voting together as a single class, were entitled to elect one member of the Board of Directors. The holders of outstanding shares of Series D, voting together as a single class, were entitled to elect one member of the Board of Directors. The Series B-1 were non-voting shares. The holders of a majority of the outstanding shares of voting common stock, voting as a separate class, were entitled to elect one member of the Board of Directors.

Dividends: Prior to and in preference of any dividends declared for common stock, the Board of Directors could elect to declare dividends on each share of Preferred Stock. Preferred stockholders were entitled to an 8% annual dividend of the original issue price per share. No dividends were declared or paid during the years ended December 31, 2025 and 2024.

Liquidation preference: In the event of any liquidation, dissolution, winding-up or liquidation event (as defined in the Company's Amended and Restated Certificate of Incorporation) of the Company, the holders of the Series D were entitled to receive, prior and in preference to any distribution of any of the proceeds of such liquidation event to the holders of any other series of Preferred Stock or common stock by reason of their ownership thereof, an amount equal to the Series D original issue price, plus all declared but unpaid dividends, on each Series D share held. After payment in full of the holders of shares of Series D, the holders of the Series C were entitled to receive, prior and in preference to any distribution of any of the proceeds of such liquidation event to the holders of Series A, Series A-1, Series B and Series B-1 or common stock by reason of their ownership thereof, an amount equal to the Series C original issue price, plus all declared but unpaid dividends, on each Series C share held. After payment in full of the holders of shares of Series D and Series C, the holders of the Series A, Series A-1, Series B and Series B-1 were entitled to receive, prior and in preference to any distribution of any of the proceeds of such liquidation event to the holders of common stock by reason of their ownership thereof, an amount equal to the original issue price of the respective series of Preferred Stock, plus all declared but unpaid dividends, on each share of Series A, Series A-1, Series B and Series B-1 held. Any remaining amounts after payment to holders of Preferred Stock would have been paid to holders of common stock.

Conversion: Each share of Preferred Stock was convertible at the option of the holder at any time after issuance into the number of fully paid and nonassessable shares of common stock as determined by dividing the

original issue price of each series of Preferred Stock by the conversion price of each series in effect at time of the conversion. The original issuance price of each series of Preferred Stock was $0.95223 per share, $1.52723 per share, $2.596 per share, $1.177506 per share, $1.07046 per share and $1.00 per share for the Series D, Series C, Series B-1, Series B, Series A-1 and Series A, respectively. The initial conversion price for each series of Preferred Stock was the respective original issue price, subject to adjustment in accordance with the anti-dilution provisions of the stock. Each share of Preferred Stock would have been automatically converted into one share of common stock at the then effective conversion rate in the event of either (i) the occurrence of an event, specified by the vote or written consent of the holders of a majority of the Series D, Series C, Series B, Series A-1 and Series A, voting together as a single class, and the holders of at least 60% of the Series D, or (ii) a qualified initial public offering at a price of at least $19.20 per share resulting in gross offering proceeds to the Company of not less than $150.0 million. In connection with the IPO in October 2025, all outstanding shares of the Company's Preferred Stock automatically converted into shares of the Company's common stock.

The Series D Agreement and the Company's then-effective Amended and Restated Certificate of Incorporation included a defaulting purchaser provision pursuant to which an investor's shares of Series D would be automatically converted into one-tenth of a share of common stock and would forfeit their preferred share rights if such investor were to fail to purchase at the Tranche 2 Closing (as defined in the Series D Agreement) the Series D shares allocated to such investor.

Redemption: The Preferred Stock was not redeemable at the option of the holders thereof.

Reissuance: Shares of any Preferred Stock that were redeemed or converted would have been retired or canceled and could not have been reissued.

11. Common Stock

In October 2025, the Board approved the amended and restated certificate of incorporation, which was filed upon the closing of the IPO and which authorized the Company to issue up to 10,000,000 shares of preferred stock, with a par value of $0.0001.

As of December 31, 2025 and 2024, the Company's amended and restated certificate of incorporation authorized the Company to issue 497,272,489 and 320,377,504 shares of voting common stock, respectively, with a par value of $0.0001. As of December 31, 2025 and 2024, the Company's amended and restated certificate of incorporation authorized the Company to issue 2,727,511 and 4,622,496 shares of non-voting common stock, respectively, with a par value of $0.0001.

The holders of the voting common stock have the right to one vote for each share of voting common stock held at all meetings of stockholders. Shares of non-voting common stock have no voting rights. Each share of the Company’s non-voting common stock may be converted at any time into one share of voting common stock at the option of its holder by providing written notice to the Company, provided that the holder will be prohibited from converting non-voting common stock into voting common stock if, as a result of such conversion, the holder, together with its affiliates, would own more than 4.99% of the total number of shares of the Company’s voting common stock then issued and outstanding, which percentage may be increased to such other percentage not to exceed 19.99% upon 61 days’ notice to the Company or decreased at any time upon notice to the Company. Dividends may be paid when, as and if declared by the Board, subject to the rights of the preferred stock to receive dividends prior and in preference to the common stock. As of December 31, 2025, no cash dividends had been declared or paid.

At December 31, 2025 and 2024, the Company had reserved the following shares of voting common stock:

Voting Common Stock	December 31, 2025	December 31, 2024
Common stock incentive awards issued and outstanding	9,142,493	4,386,606
Non-voting common stock, as converted	2,727,511	—
Common stock available for future grant under 2019 Equity Incentive Plan	—	383,378
Common stock available for future grant under 2025 Equity Incentive Plan	589,586	—
Common stock available for future issuance under employee stock purchase plan	450,000	—
Common stock reserved for future issuance under NeuroSolis, Inc. asset purchase agreement	35,476	62,083
Preferred stock, as converted	—	12,911,004
Total voting common stock reserved for future issuance	12,945,066	17,743,071

12. Stock-Based Compensation

2019 Equity Incentive Plan

On February 21, 2019, the Company adopted the 2019 Equity Incentive Plan (the "2019 Plan"). All employees, officers, directors, and consultants were eligible to be granted options to purchase common stock, restricted stock and restricted stock units under the terms of the 2019 Plan. Upon the effectiveness of the 2025 Plan (as defined below), the 2019 Plan was terminated and no further issuances were made under the 2019 Plan, although it continues to govern the terms of any equity grants that remain outstanding under the 2019 Plan.

All stock option grants were non-statutory stock options except option grants to employees (including officers and directors) intended to qualify as incentive stock options under the Internal Revenue Code of 1986, as amended. Incentive stock options could not have been granted at less than the fair market value of the Company's common stock on the date of grant, as determined in good faith by the Board at its sole discretion. Nonqualified stock options could have been granted at an exercise price established by the Board at its sole discretion (which had not been less than fair market value on the date of grant) and the vesting periods could have varied. Vesting periods were generally four years and are determined by the Board. Stock options became exercisable as they vested. Options granted under the 2019 Plan expired no more than ten years from the date of grant.

2025 Equity Incentive Plan

In October 2025, the Board adopted and approved, and the Company's stockholders approved, the 2025 Equity Incentive Plan (the "2025 Plan"), which became effective immediately prior to and contingent upon the execution of the underwriting agreement related to the Company's IPO. The 2025 Plan allows the Company to make equity-based and cash-based incentive awards to its employees, directors, and consultants. The 2025 Plan provides for the grant of incentive stock options, non-statutory stock options, stock appreciation rights, restricted stock awards, RSUs and other stock-based awards. Initially, 11,500,000 shares were reserved for issuance under the 2025 Plan, which is the sum of: (i) 4,300,000 new shares, plus (ii) up to 7,200,000 shares of common stock subject to awards granted under the 2019 Plan that, after the effective date of the 2025 Plan, expire or otherwise terminate without having been exercised in full or are forfeited or repurchased. In addition, the number of shares reserved and available for issuance under the 2025 Plan automatically increased on January 1, 2026 and will increase each January 1 thereafter through January 1, 2035, by five percent of the aggregate number of shares of common stock of all classes issued and outstanding on the immediately preceding December 31 or such lesser number of shares of common stock as determined by the Board.

The shares of common stock underlying any awards under the 2025 Plan and the 2019 Plan that are forfeited, canceled, held back upon exercise or settlement of an award to satisfy the exercise price or tax withholding, reacquired by the Company prior to vesting, satisfied without the issuance of stock, expire, or are otherwise terminated (other than by exercise) will be added back to the shares of common stock available for issuance under the 2025 Plan.

As of December 31, 2025, there were 589,586 shares of common stock available for future grants under the 2025 Plan.

2025 Employee Stock Purchase Plan

In October 2025, the Board adopted and approved, and the Company's stockholders approved, the 2025 Employee Stock Purchase Plan (the "2025 ESPP"), which became effective immediately prior to and contingent upon the execution of the underwriting agreement related to the Company's IPO. A total of 450,000 shares of common stock were initially reserved for issuance under this plan. The number of shares of common stock that may be issued under the 2025 ESPP automatically increased on January 1, 2026 and will increase each January 1 thereafter through January 1, 2035, by the lesser of one percent of the outstanding number of shares of common stock on the immediately preceding December 31 and 900,000 shares of common stock, or such lesser number of shares as determined by the Board.

No shares of the Company's common stock were issued during the year ended December 31, 2025 related to the 2025 ESPP. Stock-based compensation expense recognized during the year ended December 31, 2025 related to the 2025 ESPP was $0.1 million.

IPO Option Grants and RSU Awards

In connection with the IPO, the Company issued to certain directors, consultants and employees, including its executive officers, stock options to purchase an aggregate of 2,954,899 shares of its common stock with an exercise price of $17.00 per share, under the 2025 Plan. The Company estimated that the aggregate grant-date fair value of the options granted in connection with the IPO was $39.7 million, which is expected to be recognized as stock-based compensation expense over a period of four years. In addition, in connection with the IPO, the Company granted certain directors, consultants and employees, including its executive officers, an aggregate of 727,405 RSUs under the 2025 Plan. Based on an assumed fair value of $17.00 per share, which was the initial public offering price, the Company estimated that the aggregate grant-date fair value of the RSUs granted in connection with the IPO was $12.4 million, which is expected to be recognized as stock-based compensation expense over a period of four years.

Stock Options

A summary of the stock option activity during the year ended December 31, 2025 is as follows:

	Number of Options	Weighted Average Exercise Price	Weighted Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2024	956,667	$ 5.60	6.77	$ 12,487
Granted	2,954,899	17.00		
Exercised	(42,498)	6.71		258
Forfeited and expired	(3,687)	9.92		
Outstanding as of December 31, 2025	3,865,381	$ 14.30	8.85	$ 12,625
Options exercisable as of December 31, 2025	852,663	$ 5.30	5.65	$ 10,457

Stock Option Valuation

There were no stock options granted by the Company during the year ended December 31, 2024. The assumptions that the Company used to determine the grant-date fair value of stock options granted during the year ended December 31, 2025 were as follows:

	December 31, 2025
Risk-free interest rate	3.70%
Expected term (in years)	6.08
Expected volatility	96.57%
Expected dividend yield	0.00%

The weighted-average grant date fair value of options granted to employees during the year ended December 31, 2025 was $13.45 per share. As of December 31, 2025, unrecognized compensation cost related to unvested stock options was $38.2 million, which is expected to be recognized over a weighted average period of 3.66 years.

The total fair value of options vested was $0.8 million and $1.2 million for the years ended December 31, 2025 and 2024, respectively.

Restricted Stock Units

During the year ended December 31, 2025, the Company issued 3,615,979 restricted stock units ("RSUs"). RSUs issued under the 2025 Plan include a service condition. RSUs issued under the 2019 Plan included both service and performance conditions. The performance condition required a liquidity event in order to vest, which was satisfied in connection with the effectiveness of the IPO in October 2025. The two vesting requirements needed to be satisfied on or before the expiration date (seven years after the issue date or termination of employment) or else the RSUs would have been immediately forfeited. The RSUs could not vest in whole or in part if only one of the two requirements were satisfied on or before the expiration date.

A summary of the restricted stock unit activity during the year ended December 31, 2025 is as follows:

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested restricted stock units at December 31, 2024	3,429,939	$ 15.82
Granted	3,615,979	11.50
Vested	(1,690,801)	15.10
Cancelled	(78,005)	16.04
Unvested restricted stock units at December 31, 2025	5,277,112	$ 13.08

1,690,801 and zero RSUs vested during the years ended December 31, 2025 and 2024. Of the RSUs that vested during the year ended December 31, 2025, 1,349,275 had not settled as of December 31, 2025. As of December 31, 2025, there was $61.2 million of unrecognized stock-based compensation expense related to unvested RSUs, which is expected to be recognized over a weighted average period of 3.01 years. Stock-based compensation expense of $24.5 million related to the RSUs was recognized in connection with the effectiveness of the IPO in October 2025, which satisfied the performance condition.

Stock-Based Compensation Expense

Stock-based compensation expense included in the Company's consolidated statements of operations and comprehensive loss is as follows (in thousands):

	Year Ended December 31,	
	2025	2024
Research and development	$ 22,196	$ 597
General and administrative	13,810	483
Total stock-based compensation expense	$ 36,006	$ 1,080

13. Income Taxes

Since its inception in 2018, the Company has generated cumulative federal and state net operating loss and research and development credit carryforwards for which any net tax benefit has not been recorded due to uncertainty around utilizing these tax attributes within the respective carryforward periods.

On July 4, 2025, the One Big Beautiful Bill Act ("OBBBA") was signed into law, which includes, among other provisions, changes to the U.S. corporate income laws, including allowing the immediate expensing of certain qualifying research and development costs and the permanent extension of certain provisions within the Tax Cuts and Jobs Act. The impacts of the OBBBA did not have a material impact on the 2025 consolidated financial statements, and the Company will continue to evaluate its impacts in future periods.

For the year ended December 31, 2025, the Company adopted ASU 2023-09 on a prospective basis. A reconciliation of the U.S. federal statutory rate to the Company's effective tax rate for the year ended December 31, 2025, after the adoption of ASU 2023-09, is as follows (in thousands):

	December 31, 2025	
	Dollars	Percent
U.S. federal statutory income tax rate	$ (33,842)	21.0%
Tax credits		
Research and development credit	(5,373)	3.3
Change in valuation allowance	39,359	(24.4)
Nontaxable or nondeductible	189	(0.1)
Other	(333)	0.2
Effective income tax rate	$ —	0.0%

A reconciliation of the U.S. federal statutory rate to the Company's effective tax rate for the years ended December 31, 2024, prior to the adoption of ASU 2023-09, was as follows:

	December 31,
	2024
U.S. federal statutory income tax rate	21.0%
State and local taxes, net of federal benefit	1.0
Change in state tax rate	(0.6)
Change in valuation allowance	(25.3)
Permanent items	—
Research and development credits	3.9
Other	—
Effective income tax rate	0.0%

The Company's total deferred tax assets at December 31, 2025 and December 31, 2024 are as follows (in thousands):

	December 31,	
	2025	2024
Deferred tax assets		
Capitalized R&D costs	$ 44,867	$ 24,992
Net operating losses	21,107	12,972
R&D credit carryforwards	13,473	8,055
Stock-based compensation expense	6,720	396
Other	3,320	3,499
Total deferred tax assets	89,487	49,914
Less: valuation allowance	(89,487)	(49,914)
Net deferred tax asset	$ —	$ —

As of the years ended December 31, 2025 and 2024, the Company had federal net operating loss carryforwards of $96.6 and $58.6 million, respectively, and state operating loss carryforwards of $13.1 million and $10.5 million, respectively, which may be available to offset future taxable income. The U.S. federal net operating loss carryforwards do not expire but are subject to 80% limitation and are available to reduce future taxable income indefinitely. The state net operating loss carryforwards are available to offset future taxable income and begin to expire in 2039. At December 31, 2025, the Company had federal and state research and development tax credit carryforwards of $13.3 and $0.2 million, respectively. At December 31, 2024, the Company had federal and state research and development tax credit carryforwards of $8.0 million and $0.1 million, respectively.

Pursuant to Section 382 of the Internal Revenue Code, and similar state tax law, certain substantial changes in the Company's ownership may result in a limitation on the amount of net operating loss carryforwards and tax carryforwards that may be used in future years. Utilization of the net operating loss ("NOL") and tax credit carryforwards may be subject to a substantial annual limitation under Section 382 of the Internal Revenue Code of 1986 due to ownership change limitations that have occurred previously or that could occur in the future. These ownership changes may limit the amount of NOL and tax credit carryforwards that can be utilized annually to offset future taxable income and tax, respectively. The Company has completed a Section 382 study through December 31, 2025, and identified one ownership change in 2019 that did not have a material impact on the Company’s tax attributes. The Company will continue to evaluate changes in ownership and the related limitations on a go forward basis.

ASC 740 requires a valuation allowance to reduce the deferred tax assets reported if, based on the weight of the evidence, it is more likely than not that some portion or all of the deferred tax assets will not be realized. After consideration of all the evidence, both positive and negative, the Company recorded a valuation allowance against deferred tax assets at December 31, 2025 because the Company determined that it is more likely than not that the Company will not recognize the benefits of the Company's federal and state deferred tax assets primarily due to the Company's cumulative loss position and, as a result of the net change in the total valuation allowance between 2025 and 2024 resulted in an increase of $39.6 million.

The Company applies the authoritative guidance on accounting for and disclosure of uncertainty in tax positions, which requires the Company to determine whether a tax position of ours is more likely than not to be sustained upon examination, including resolution of any related appeals of litigation processes, based on the technical merits of the position. For tax positions meeting the more likely than not threshold, the tax amount recognized in the financial statements is reduced by the largest benefit that has a greater than fifty percent likelihood of being realized upon the ultimate settlement with the relevant taxing authority. As of the years ended December 31, 2025 and 2024, the Company had no unrecognized tax benefits. The Company's policy is to record interest and penalties related to income taxes as a component of income tax expense. As of the years ended December 31, 2025 and 2024, the Company had no accrued interest or penalties related to income taxes and no amounts have been recognized in the Company's statement of operations and comprehensive loss.

The Company files income tax returns in the U.S., Massachusetts, and California. The statute of limitations for assessment by the Internal Revenue Service and Massachusetts tax authorities remains open for all years since 2019.

To the extent the Company has tax attribute carryforwards, the tax years in which the attribute was generated may still be adjusted upon examination by the Internal Revenue Service or state authorities to the extent utilized in a future period. No federal or state tax audits are currently in process.

14. Net Loss Per Share

Basic net loss per share attributable to common stockholders was calculated as follows (in thousands, except share and per share amounts):

	Year Ended December 31,	
	2025	2024
Numerator:		
Net loss	$ (161,152)	$ (77,580)
Denominator:		
Weighted-average number of common shares outstanding - basic and diluted	8,680,741	736,178
Net loss per share - basic and diluted	$ (18.56)	$ (105.38)

The Company's potentially dilutive securities have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share. 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 Company excluded the following shares from the computation of diluted net loss per share attributable to common stockholders as of December 31, 2025 and 2024 because including them would have had an anti-dilutive effect:

	Year Ended December 31,	
	2025	2024
Unvested restricted stock units	5,277,112	3,429,939
Options to purchase common stock	3,865,381	956,667
Employee stock purchase plan	17,736	—
Redeemable convertible preferred stock	—	12,911,004
Total	9,160,229	17,297,610

15. Commitments and Contingencies

Legal Proceedings

The Company may, from time to time, be party to litigation arising in the ordinary course of business. The Company was not subject to any material legal proceedings as of December 31, 2025, and no material legal proceedings are currently pending or, to the best of the Company's knowledge, threatened.

Contractual Obligations

NeuroSolis, Inc. asset purchase agreement

Pursuant to the asset purchase agreement the Company entered into with NeuroSolis, Inc. to acquire its proprietary M_1/M_4 agonist molecules and associated intellectual property, the Company had an obligation to potentially issue up to an aggregate of 62,083 shares of the Company's common stock, contingent upon the occurrence of specified development and regulatory milestones. In June 2025, the Company issued 26,607 shares of common stock to NeuroSolis, Inc. upon the initiation of a Phase 2 clinical trial for ML-007C-MA. As of December 31, 2025, the range of additional shares to be issued is between 0 and 35,476, and the issuance of these shares is reasonably possible if certain milestones are met.

Michael J. Fox Foundation grant agreements (Note 16)

The Company may be obligated to make future payments under grant agreements with the Michael J. Fox Foundation, restricted to two times the grant awards received, contingent upon certain net product sales. As of December 31, 2025, the Company was unable to estimate the timing or likelihood of generating the associated future product sales.

Universities and other third parties

The Company may be obligated to make future payments, in addition to nominal annual maintenance fees, under license and collaboration agreements with Stanford University, other universities and other third parties upon the occurrence of future events such as the Company's achievement of specified regulatory and commercial milestones or royalties on net sales. As of December 31, 2025, the Company was unable to estimate the timing or likelihood of achieving these milestones or generating future product sales.

Guarantees

The Company is a party to a number of agreements entered into in the ordinary course of business that contain typical provisions that obligate the Company to indemnify the other parties to such agreements upon the occurrence of certain events. Such indemnification obligations are usually in effect from the date of execution of the applicable agreement for a period equal to the applicable statute of limitations. The aggregate maximum potential future liability of the Company under such indemnification provisions is uncertain.

As of December 31, 2025, the Company had not experienced any losses related to these indemnification obligations, and no material claims with respect thereto were outstanding. The Company does not expect significant claims related to these indemnification obligations and, consequently, concluded that the fair value of these obligations is negligible, and no related reserves have been established.

License Agreement

The Company has entered into a license agreement under which it is obligated to make fixed and contingent payments, as described in Note 9.

16. Employee Benefit Plan

The Company's employees are eligible to participate in the Company's 401(k) retirement plan (the "401(k) Plan"). Participants may contribute up to 100% of their annual compensation to the 401(k) Plan, subject to statutory limitations. The 401(k) Plan has a safe harbor match. The Company made matching contributions of up to 4% of the eligible employee's compensation for the years ended December 31, 2025 and 2024. The Company's contributions for the years ended December 31, 2025 and 2024 were $0.8 million and $0.6 million, respectively.

17. Grants

Between February 2020 and August 2022, the Company executed four grant agreements (the "Grants") with the Michael J. Fox Foundation for the purpose of researching Parkinson's disease. The Grants consisted of two-year and three-year research programs totaling $25.7 million.

The Grants are payable in installments over the term of the grant according to certain research milestones and progress reports. Funds received for the purchase of property and equipment are accounted for as a reduction to the carrying value of the corresponding asset. Funds received for the reimbursement of expenses incurred related to research and development are accounted for as a reduction to the associated expense. Funds received prior to corresponding asset purchase or incurred expense are recorded as a deferred grant liability on the consolidated balance sheets.

Grant earnings recognized during the years ended December 31, 2025 and 2024 were $3.2 million and $1.0 million, respectively. Deferred grant earnings as of December 31, 2025 and 2024 were zero and $3.2 million, respectively. The Company did not recognize any grant earnings as a reduction to the carrying value of property and equipment purchased for the years ended December 31, 2025 and 2024.

18. Related Party Transactions

In October 2023, the Company entered into an Assignment and Assumption Agreement with Stellaromics. The Company determined that Stellaromics is a related party. Refer to Note 8 for further details.

Also in October 2023, Catalyst4, Inc. ("Catalyst") became the largest stockholder of Stellaromics, holding a minority interest of its outstanding capital stock. As of December 31, 2025, Catalyst holds a controlling interest of the outstanding capital stock of Stellaromics. Catalyst is also the largest stockholder of the Company and owned a minority interest and controlling interest of the Company's outstanding shares as of December 31, 2025 and 2024, respectively. In addition, prior to the Stellaromics Agreement, Christopher A. Kroeger, M.D., the Company's Chief Executive Officer, was designated to be a director on the board of directors of Stellaromics. Dr. Kroeger is also an equity holder of Stellaromics. Dr. Kroeger's position on the board of directors of Stellaromics is determined by the stockholders holding a majority of the shares of common stock and preferred stock outstanding of Stellaromics. The Company does not have contractual rights to nominate any members to the Stellaromics board of directors.

In February 2019, the Company entered into an advisor agreement with a member of the Board, pursuant to which the Board member receives monthly payments in exchange for his service on the Company's scientific advisory board. The Company recorded $0.1 million and $0.1 million of research and development expense in the consolidated statements of operations and comprehensive loss during the years ended December 31, 2025 and 2024, respectively, relating to the member's service on the Company's scientific advisory board.

The spouse of an executive officer of the Company was employed by the Company from November 2023 to April 2025. The spouse's annual salary was recorded in research and development expense in the consolidated statements of operations and comprehensive loss. During the year ended December 31, 2025, the spouse's compensation, which consisted of annual salary and RSU grants, was de minimis. During the year ended December 31, 2024, the spouse's compensation was approximately $0.3 million.

19. Segment Information

The Company manages its operations as a single reportable segment focused on the research and development of product candidates. The accounting policies of the single reportable segment are identical to those described in Note 2. The chief operating decision maker, who manages the Company's operations on a consolidated basis, assesses performance for the reportable segment using consolidated net loss to monitor budget versus actual results and to determine how to effectively allocate the Company's resources. The measure of segment assets is reported on the consolidated balance sheets as total consolidated assets. The following table presents certain financial data for the Company's reportable segment for the years ended December 31, 2025 and 2024 (in thousands):

	Year Ended December 31,	
	2025	2024
Clinical trial expenses	$ 53,461	$ 18,180
Employee-related research and development expenses	51,062	21,337
Chemistry, manufacturing and controls expenses	18,266	11,473
Preclinical program expenses	10,421	13,972
Other research and development expenses	5,139	3,561
Employee-related general and administrative expenses	21,688	7,457
Professional fees and other general and administrative expenses	9,046	6,966
Other segment items[(1)]	(7,931)	(5,366)
Net loss	$ 161,152	$ 77,580

(1) Other segment items include interest income, loss from equity method investment, and other income, net.