2025 Annual Report

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 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 001-33185

MEDICINOVA, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**33-0927979**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**
4275 Executive Square, Suite 300, La Jolla, CA	**92037**
(Address of Principal Executive Offices)	**(Zip Code)**

(858) 373-1500

(Registrant's Telephone Number, Including Area Code)

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

Title of Each Class	Trading Symbol	Name of Each Exchange on Which Registered
Common Stock, par value $0.001 per share	MNOV	The Nasdaq Stock Market LLC

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

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

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

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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

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

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

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

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

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

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

The aggregate market value of the registrant's common stock held by non-affiliates of the registrant was approximately $62,397,025 based on the closing price of the registrant's common stock on the Nasdaq Global Market of $1.31 per share on June 30, 2025. Shares of common stock held by each executive officer and director and each affiliated entity has been excluded from this calculation. This determination of affiliate status may not be conclusive for other purposes.

The number of outstanding shares of the registrant's common stock, par value $0.001 per share, as of March 5, 2026 was 49,221,246.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement to be filed with the Securities and Exchange Commission pursuant to Regulation 14A in connection with the registrant's 2026 Annual Meeting of Stockholders, which will be filed subsequent to the date hereof, are incorporated by reference into Part III of this Form 10-K.

MEDICINOVA, INC.

FORM 10-K—ANNUAL REPORT

For the Fiscal Year Ended December 31, 2025

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PART I

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K includes forward-looking statements that involve a number of risks and uncertainties, many of which are beyond our control. The forward-looking statements are contained principally in the sections titled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations," but are also contained elsewhere in this report. Forward-looking statements include all statements that are not historical facts and, in some cases, can be identified by terms such as "believe," "may," "will," "estimate," "continue," "anticipate," "design," "intend," "expect," "could," "plan," "potential," "predict," "seek," "should," "would" or the negative version of these words and similar expressions.

Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including those described in "Risk Factors" and elsewhere in this report. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Also, forward-looking statements represent our beliefs and assumptions only as of the date of this report. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. You should read this report completely and with the understanding that our actual future results may be materially different from what we expect.

The following factors are among those that may cause actual results to differ materially from our forward-looking statements:

- Inability to raise additional capital if needed;
- Inability to generate revenues from product sales to continue business operations;
- Inability to develop and commercialize our product candidates;
- Failure or delay in completing clinical trials or obtaining United States Food and Drug Administration (FDA) or foreign regulatory approval for our product candidates in a timely manner;
- Unsuccessful clinical trials stemming from clinical trial designs, failure to enroll a sufficient number of patients, undesirable side effects and other safety concerns;
- Inability to demonstrate sufficient efficacy of product candidates;
- Reliance on the success of our MN-166 (ibudilast) and MN-001 (tipelukast) product candidates;
- Delays in commencement or completion of clinical trials or suspension or termination of clinical trials;
- Loss of our licensed rights to develop and commercialize a product candidate as a result of the termination of the underlying licensing agreement;
- Competitors may develop products rendering our product candidates obsolete and noncompetitive;
- Inability to successfully attract partners and enter into collaborations on acceptable terms;
- Dependence on third parties to conduct clinical trials and to manufacture product candidates;
- Dependence on third parties to market and distribute products;

- Our product candidates, if approved, may not gain market acceptance or obtain adequate coverage for third party reimbursement;
- Disputes or other developments concerning our intellectual property rights;
- Actual and anticipated fluctuations in our quarterly or annual operating results;
- Price and volume fluctuations in the overall stock markets;
- The impact of health epidemics on our business and operations;
- Litigation or public concern about the safety of our potential products;
- International trade or foreign exchange restrictions, increased tariffs, foreign currency exchange;
- High quality material for our products may become difficult to obtain or expensive;
- Strict government regulations on our business;
- Regulations governing the production or marketing of our product candidates;
- Loss of, or inability to attract, key personnel; and
- Economic, political, foreign exchange and other risks associated with international operations.

Unless the context requires otherwise, references in this Annual Report on Form 10-K to "MediciNova," "we," "us" and "our" refer to MediciNova, Inc.

Summary Risk Factors

The following is a summary of the principal risks and uncertainties that could adversely affect our business, cash flows, financial condition and/or results of operations, and these adverse impacts may be material. This summary is qualified in its entirety by reference to the more detailed descriptions of the risks and uncertainties included in Item 1A below and you should read this summary together with those more detailed descriptions.

These principal risks and uncertainties relate to, among other things:

Risks Related to Our Business and our Industry:

- the significant operating losses we have incurred and expect to incur for the foreseeable future;
- our ability to obtain the capital necessary to fund our operations;
- we do not have any products that are approved for commercial sale and do not expect to generate any revenues from product sales for the foreseeable future, if ever;
- our dependence on the success of our MN-166 (ibudilast) and MN-001 (tipelukast) product candidates and uncertainty that these product candidates will receive regulatory approval or be successfully commercialized;
- the complexity and uncertainty relating to progressing product candidates through the various stages of clinical trials and obtaining regulatory approval;

- our attempts to develop MN-001 (tipelukast) in NASH (as defined below) and NAFLD (as defined below) may detract from our efforts to develop other product candidates;
- the complexity, high cost and uncertainty of obtaining regulatory approval;
- the stringent regulation of our product candidates;
- future development and regulatory difficulties even if we are successful in receiving regulatory approval of one or more of our product candidates;
- undesirable side effects of any product candidate experienced during clinical trials could delay or prevent regulatory approval or commercialization or limit its commercial potential;
- delays in the commencement or completion of clinical trials, or suspension or termination of our clinical trials;
- the loss of any rights to develop and market any of our product candidates;
- the impact of health epidemics or any other public health crisis on our business and operations;
- our dependence on strategic collaborations with third parties to develop and commercialize product candidates;
- our reliance on third parties to conduct our clinical trials;
- our reliance on third party manufacturers to produce our product candidates;
- our, or our third party manufacturer's ability to manufacture our product candidates in commercial quantities;
- the commercial availability of materials necessary to manufacture our product candidates;
- the acceptance among physicians, patients and the medical community of our product candidates;
- the ability of users of our products to obtain adequate coverage of and reimbursement for our products from government and other third party payers;
- our ability to retain, motivate and attract key personnel;
- our ability to establish sales, marketing and distribution capabilities;
- health care reform measures could adversely affect our business;

- the impact of any product liability lawsuits against us;
- the impact of fluctuations in our results of operations;
- the cost of and management attention required to operate as a public company;
- information technology systems failures, network disruptions, breaches in data security and computer crime and cyber-attacks; and
- the complexity of operating our business and marketing our products internationally.

Risks Related to Our Intellectual Property:

- our ability to compete depends on the adequate protection of our proprietary rights;
- the potential disclosure of our trade secrets and other proprietary information; and
- the costs and uncertainties of any dispute concerning the infringement or misappropriation of our proprietary rights or the proprietary rights of others, including trade secrets.

Risks Related to the Securities Markets and Investments in Our Common Stock:

- volatility in our stock price;
- the potential delisting of our common stock on the Nasdaq Global Market or the Standard Market of the Tokyo Stock Exchange;
- the possibility of substantial dilution to our existing stockholders and/or the decline in price of our common stock if we were to sell additional shares of our common stock, including under our existing at-the-market issuance sales agreement;
- the cost of and management distraction if we were to face securities class action litigation; and
- the anti-takeover provisions in our charter documents and under Delaware law may make it difficult for third parties to acquire us or remove and replace our directors and management.

Item 1. Business

Overview

We are a biopharmaceutical company focused on developing novel therapeutics for the treatment of serious diseases with unmet medical needs and a commercial focus on the United States (U.S.) market. Our current strategy is to focus our development activities on MN-166 (ibudilast) for neurological and other disorders such as progressive multiple sclerosis (MS), amyotrophic lateral sclerosis (ALS), chemotherapy-induced peripheral neuropathy, degenerative cervical myelopathy, glioblastoma, and prevention of acute respiratory distress syndrome (ARDS), and MN-001 (tipelukast) for fibrotic and other metabolic disorders such as nonalcoholic fatty liver disease (NAFLD), and hypertriglyceridemia.

Progressive Multiple Sclerosis:

We completed a Phase 2b clinical trial of MN-166 (ibudilast) for the treatment of relapsing MS, in which positive safety and neuroprotective efficacy indicators were observed. The data from this trial indicated that MN-166 (ibudilast) may have potential in the treatment of progressive MS.

We partnered with investigators on a Phase 2b clinical trial of MN-166 (ibudilast) in primary progressive and secondary progressive MS which was conducted by NeuroNEXT and funded by the National Institute of Health's (NIH) National Institute of Neurological Diseases and Stroke (NINDS). This progressive MS trial, known as SPRINT-MS, completed randomization of 255 subjects in 2015, which exceeded the goal of 250 subjects that were planned for participation. In October 2017, we announced the presentation of positive top-line results from the SPRINT-MS Phase 2b clinical trial of MN-166 (ibudilast) in progressive MS. The trial achieved both primary endpoints of whole brain atrophy and safety and tolerability. MN-166 (ibudilast) demonstrated a statistically significant 48% reduction in the rate of progression of whole brain atrophy compared to placebo (p=0.04) as measured by magnetic resonance imaging (MRI) analysis using brain parenchymal fraction (BPF) and there was not an increased rate of serious adverse events in the MN-166 (ibudilast) group compared to the placebo group. In February 2018, we announced the presentation of positive clinical efficacy trends from this trial regarding the important secondary endpoint of confirmed disability progression. MN-166 (ibudilast) demonstrated a 26% reduction in the risk of confirmed disability progression compared to placebo (hazard ratio=0.74), as measured by Expanded Disability Status Scale (EDSS). Results of the SPRINT-MS Phase 2b clinical trial of MN-166 (ibudilast) in progressive MS were published in the New England Journal of Medicine in August 2018. In April 2019, we announced results from a subgroup analysis of the SPRINT-MS Phase 2b trial of MN-166 (ibudilast) in progressive MS which showed that the trends for reduction in the risk of confirmed disability progression were highest for the subgroup of subjects with secondary progressive MS without relapse, in which MN-166 (ibudilast) demonstrated a 46% risk reduction compared to placebo. Additional data from the completed SPRINT-MS Phase 2b trial of MN-166 (ibudilast) in progressive MS was presented in May 2019 at the American Academy of Neurology (AAN) 71st Annual Meeting in Philadelphia, Pennsylvania. In November 2020, we announced that positive Optical Coherence Tomography (OCT) results from the SPRINT-MS Phase 2b trial of MN-166 (ibudilast) in progressive MS were published in *Multiple Sclerosis Journal*. In July 2021, we received a Notice of Allowance from the U.S. Patent and Trademark Office (USPTO) for a new patent which covers MN-166 (ibudilast) for the treatment of an ophthalmic disease/disorder or injury associated with a neurodegenerative disease/disorder or a neuro-ophthalmologic disorder.

The FDA has granted Fast Track designation for the development of MN-166 (ibudilast) for the treatment of patients with progressive MS.

Amyotrophic Lateral Sclerosis:

We initiated a clinical trial of MN-166 (ibudilast) in amyotrophic lateral sclerosis (ALS) in the second half of 2014, and this trial was completed during the second half of 2017. In December 2017, we announced positive top-line results from this trial. The trial achieved the primary endpoint of safety and tolerability. In addition, there was a higher rate of responders on the Amyotrophic Lateral Sclerosis Functional Rating Scale-Revised (ALSFRS-R) total score, a measure of functional activity, in the MN-166 (ibudilast) group compared to the placebo group. In September 2018, we received feedback from the FDA regarding our clinical development plan for MN-166 (ibudilast) in ALS. In January 2019, we received a Notice of Allowance from the USPTO for a new patent which covers the combination of MN-166 (ibudilast) and riluzole for the treatment of ALS and other neurodegenerative diseases. In April 2019, we announced that the FDA completed its review of the protocol and determined that we may proceed with a Phase 2b/3 clinical trial of MN-166 (ibudilast) in ALS. In June 2019, we announced a kick-off meeting for the Phase 2b/3 clinical trial of MN-166 (ibudilast) in ALS, referred to as the COMBAT-ALS trial. In December 2019, we announced that additional analyses of the completed clinical trial of MN-166 (ibudilast) in ALS was presented at the 30th International Symposium on amyotrophic lateral sclerosis/motor neuron disease (ALS/MND) in Perth, Australia. In December 2021, we announced that a poster with an overview of our ongoing Phase 2b/3 clinical trial of MN-166 (ibudilast) in ALS was presented at the 32nd International Symposium on ALS/MND. In December 2024, a study update and interim analysis of phase 2/3 clinical data of MN-166 (ibudilast) in the COMBAT-ALS trial was presented at the 35th international symposium on ALS/MND at

Montreal, Canada. In September 2025, we announced the completion of patient enrollment in the COMBAT-ALS Phase 2/3 clinical trial, evaluating MN-166 (ibudilast) for the treatment of ALS. A total of 234 patients have been randomized across two treatment arms at multiple clinical sites in the United States and Canada. In December 2025, we announced the study update and patient characteristics of the COMBAT-ALS phase 2/3 clinical trial at the 36th International Symposium of ALS/MND at San Diego, California.

The FDA has granted Fast Track designation to MN-166 (ibudilast) for the treatment of ALS as well as Orphan-Drug designation for the treatment of ALS, which will provide seven years of marketing exclusivity if it is approved for ALS. The European Commission also granted Orphan Medicinal Product Designation for MN-166 (ibudilast) for the treatment of ALS.

Degenerative Cervical Myelopathy: In August 2018, we announced plans to initiate a clinical trial of MN-166 (ibudilast) in degenerative cervical myelopathy (DCM) in collaboration with the University of Cambridge. The trial is funded by a grant from the National Institute for Health Research (NIHR) in the United Kingdom (UK). In May 2019, we announced our participation at the Kick-off Meeting for the Phase 3 clinical trial in DCM, "REgeneration in CErvical DEgenerative Myelopathy (RECEDE Myelopathy)" in collaboration with University of Cambridge researchers. In February 2022, we announced that MN-166 (ibudilast) was discussed as a potential beneficial pharmacological agent for the treatment of DCM in *Global Spine Journal*.

Glioblastoma: We have initiated clinical development to evaluate MN-166 (ibudilast) for the treatment of glioblastoma. In June 2017, we announced positive results from an animal model study that examined the potential clinical efficacy of MN-166 (ibudilast) for the treatment of glioblastoma. These results were presented at the 2017 American Society of Clinical Oncology (ASCO) Annual Meeting. In May 2018, we announced that the Investigational New Drug Application (IND) for MN-166 (ibudilast) for treatment of glioblastoma was accepted and opened with the FDA. In October 2018, we announced that the FDA granted orphan-drug designation to MN-166 (ibudilast) as adjunctive therapy to temozolomide for the treatment of glioblastoma. In January 2019, we announced the initiation of enrollment in a clinical trial of MN-166 (ibudilast) in combination with temozolomide for the treatment of glioblastoma at the Dana-Farber Cancer Institute in Boston. In February 2019, we announced that *Scientific Reports* published results from the animal model study evaluating MN-166 (ibudilast) in glioblastoma. In June 2020, we announced that positive preclinical findings were published in *Frontiers in Immunology* regarding the prospect of MN-166 (ibudilast) as an adjunctive treatment for glioblastoma. In August 2021, we announced completion of a safety review of Part 1 of the Phase 2 clinical trial of MN-166 (ibudilast) in combination with temozolomide, which enrolled 15 subjects with recurrent glioblastoma. There were no concerning safety signals observed in Part 1 and there were no serious adverse events related to MN-166 (ibudilast). Five out of 15 subjects completed cycle 6 without disease progression, i.e. 33% of the subjects were progression-free at six months. In April 2022, we announced that data demonstrating that MN-166 (ibudilast) prevents metastasis in a uveal melanoma (UM) animal model was published in the journal *Molecular Cancer Research*. In January 2023, we announced that the Phase 2 clinical trial evaluating MN-166 (ibudilast) in combination with temozolomide in glioblastoma at the Dana-Farber Cancer Institute had completed enrollment. In February 2023, we announced the presentation of new data regarding a tumor tissue analysis from this clinical trial at the 20th Annual World Congress of Society for Brain Mapping and Therapeutics (SBMT). In November 2023, we announced new data and results of the Phase 2 clinical trial of MN-166 (ibudilast) in glioblastoma patients at the 28th Annual Meeting of the Society for Neuro-Oncology (SNO). The presentation also included data from preclinical studies which evaluated the combination of MN-166 (ibudilast) and anti-PD1 or anti-PD-L1 therapy in glioblastoma models. In 2024, we presented new data and results of a Phase 1b/2a Clinical Trial of MN-166 (ibudilast) in glioblastoma at the ASCO Annual meeting 2024 held in Chicago, IL.

Prevention of ARDS in patients with COVID-19: In March 2020, we announced plans to initiate development of MN-166 (ibudilast) for severe pneumonia and ARDS based on positive results of a preclinical study in an animal model of ARDS. In April 2020, we announced plans to initiate a clinical trial of MN-166 (ibudilast)

for ARDS caused by COVID-19. In July 2020, we announced that the IND for MN-166 (ibudilast) for prevention of ARDS was accepted and opened with the FDA. We were also informed by the FDA that the proposed clinical investigation of MN-166 (ibudilast) for the prevention of ARDS in patients with COVID-19 may proceed. In April 2022, we announced that the Phase 2 clinical trial of MN-166 (ibudilast) in hospitalized COVID-19 patients at risk for developing ARDS had completed enrollment. In June 2022, we announced positive top-line results from this Phase 2 clinical trial. MN-166 (ibudilast) demonstrated large improvements compared to placebo for all four clinical endpoints analyzed. The trial achieved statistical significance for one of the co-primary endpoints, the proportion of subjects free of respiratory failure. The trial also achieved statistical significance for the proportion of subjects discharged from the hospital. There were two deaths in the placebo group and no deaths in the MN-166 (ibudilast) group. In July 2022, we announced the initiation of a first-in-human clinical study to evaluate a new parenteral (injectable) formulation of MN-166 (ibudilast). In January 2023, we announced that this Phase I clinical trial of MN-166 (ibudilast) 10 mg intravenous (IV) infusion in healthy volunteers was completed with a favorable safety profile and was well tolerated.

MN-001 (tipelukast) is in development for fibrotic and other metabolic disorders as described below.

Nonalcoholic Steatohepatitis (NASH) and Nonalcoholic Fatty Liver Disease (NAFLD): We announced positive results of MN-001 (tipelukast) in two different NASH mouse models in 2014 and we opened the IND (Investigational New Drug) application for MN-001 (tipelukast) for the treatment of NASH with the FDA in 2015. The FDA subsequently granted Fast Track designation to MN-001 (tipelukast) for the treatment of patients with NASH with fibrosis. We then initiated a clinical trial to investigate MN-001 (tipelukast) for the treatment of hypertriglyceridemia in NASH and NAFLD patients. In April 2018, we announced that we would terminate this trial early after positive results from an interim analysis in which MN-001 (tipelukast) significantly reduced mean serum triglycerides, a primary endpoint. This data was presented at the International Liver Congress 2018, the 53rd annual meeting of the European Association for the Study of the Liver (EASL) in Paris, France in April 2018. In November 2020, we announced positive results of in-vitro and in-vivo studies that evaluated MN-001 (tipelukast) for its anti-liver fibrotic effect in human hepatic stellate cells (HSCs) and in an acute liver injury model at the annual meeting of the American Association for the Study of Liver Diseases (AASLD). In November 2021, we announced new findings from a study that investigated the mechanism by which MN-001 (tipelukast) alters triglyceride metabolism in hepatocytes at the Annual Meeting of the American Association for the Study of Liver Diseases (AASLD). In April 2022, we announced that the FDA completed its review of a proposed Phase 2 clinical trial to evaluate MN-001 (tipelukast) for the treatment of patients with NAFLD, type 2 diabetes mellitus, and hypertriglyceridemia and the study may proceed. In July 2022, we announced the initiation of a Phase 2 clinical trial to evaluate MN-001 (tipelukast) for the treatment of patients with NAFLD, type 2 diabetes mellitus, and hypertriglyceridemia. In December 2022, we announced the presentation of positive results from a subgroup analysis of the completed Phase 2 clinical trial which evaluated MN-001 (tipelukast) in participants with NAFLD and hypertriglyceridemia (HTG) at the International Diabetes Federation (IDF) World Diabetes Congress 2022. In May 2024, we presented an update of ongoing trial design at the 92nd European Atherosclerosis Society (EAS) 2024 Congress.

Our Strategy

Our goal is to build a sustainable biopharmaceutical business through the successful development of differentiated products for the treatment of serious diseases with unmet medical needs in high-value therapeutic areas. Key elements of our strategy are as follows:

- *Pursue the development of MN-166 (ibudilast) for multiple potential indications with the support of non-dilutive financings.*

We intend to advance our diverse MN-166 (ibudilast) program through a combination of investigator-sponsored clinical trials, trials funded through government grants or other grants, and trials funded by us. We intend to pursue additional strategic alliances to help support further clinical development of MN-166 (ibudilast).

- *Pursue the development of MN-001 (tipelukast) for fibrotic and other metabolic disorders.*

We intend to advance development of MN-001 (tipelukast) through a variety of means, which may include investigator-sponsored trials with or without grant funding as well as trials funded by us.

- *Consider strategic partnerships with one or more leading pharmaceutical companies to complete product development and successfully commercialize our products.*

We develop and maintain relationships with pharmaceutical companies that are therapeutic category leaders. We intend to discuss strategic alliances with leading pharmaceutical companies who seek product candidates, such as MN-166 (ibudilast) and MN-001 (tipelukast), which could support our clinical development and product commercialization.

Our Product Candidates and Programs

Our product development programs address diseases that we believe are not well served by currently available therapies and represent significant commercial opportunities. We believe that we have product candidates that offer innovative therapeutic approaches that may provide significant advantages relative to current therapies.

Our product acquisitions have focused primarily on product candidates with significant preclinical and early clinical testing data that have been developed by the licensors outside of the United States. We utilize the existing data in preparing IND Applications or their foreign equivalents, and in designing and implementing additional preclinical or clinical trials to advance the development programs in the United States or abroad.

Following are the details of our product development programs:

MN-166 (ibudilast)

MN-166 (ibudilast) is a novel, first-in-class, oral, anti-inflammatory and neuroprotective agent. MN-166 (ibudilast) inhibits macrophage migration inhibitory factor (MIF) and certain phosphodiesterases (PDEs). MN-166 (ibudilast) also attenuates activated glia cells, which play a major role in certain neurological conditions. While it has been in use for more than 40 years in Japan and Korea for the treatment of asthma and post-stroke dizziness, we are developing MN-166 (ibudilast) for the treatment of progressive MS, ALS, degenerative cervical myelopathy, glioblastoma, and prevention of acute respiratory distress syndrome. We licensed MN-166 (ibudilast) from Kyorin Pharmaceuticals (Kyorin) in 2004.

The FDA has granted Fast Track designations to MN-166 (ibudilast) for two separate indications: the treatment of progressive MS and the treatment of ALS. Fast track designation is a process designed to facilitate the development and expedite the review of drugs that are intended to treat serious diseases and have the potential to fill an unmet medical need. An important feature of the FDA's Fast Track program is that it emphasizes early and frequent communication between the FDA and the sponsor throughout the entire drug development and review process to improve the efficiency of product development. Accordingly, Fast Track status can potentially lead to a shortened timeline to ultimate drug approval.

The FDA has granted Orphan-Drug designation to MN-166 (ibudilast) for the treatment of ALS, which will provide seven years of marketing exclusivity if it is approved for ALS in the U.S. The European Commission also granted Orphan Medicinal Product Designation for MN-166 (ibudilast) for the treatment of ALS which offers potential benefits including ten years of marketing exclusivity if it is approved for ALS in Europe. The FDA has

also granted Orphan-Drug designation to MN-166 (ibudilast) as adjunctive therapy to temozolomide for the treatment of glioblastoma.

We have filed patent applications for multiple uses of MN-166 (ibudilast) for the treatment of neurological conditions. Some of the patent estate has received allowance in the United States and foreign countries. For example, we have been granted separate U.S. patents that cover the use of MN-166 (ibudilast) for the treatment of progressive MS, for the treatment of ALS, and for the treatment of glioblastoma.

Progressive Multiple Sclerosis: MS is a complex disease with predominantly unknown etiology and affects approximately 2.8 million people worldwide, according to the National Multiple Sclerosis Society (NMSS). Also, according to NMSS, approximately 85 percent of people with MS are initially diagnosed with relapsing-remitting MS (RRMS) and some people who are initially diagnosed with RRMS will eventually transition to secondary progressive MS (SPMS). About 15 percent of people with MS are diagnosed with primary progressive MS (PPMS). There is only one approved drug for PPMS and it is administered by intravenous infusion. Although several drugs have been approved for SPMS with relapses, there are no approved drugs generally considered safe and efficacious for SPMS in the absence of relapses. There is a significant medical need for a safe, effective, and conveniently administered therapy for patients with PPMS and SPMS and the unmet medical need is highest in patients with SPMS without relapses. MN-166 (ibudilast) may meet these needs.

Based on promising results from a Phase 2 trial in relapsing MS completed in 2008, investigators from NeuroNEXT, a NIH-funded Phase 2 clinical trial network, evaluated MN-166 (ibudilast) in PPMS and SPMS patients in the United States. SPRINT-MS is the name of the Phase 2b, randomized, double-blind, placebo-controlled trial that evaluated the safety and tolerability of MN-166 (ibudilast) (up to 100 mg/day) in PPMS and SPMS patients. Recruitment and enrollment at 28 medical centers in the United States commenced in late 2013 and randomization of 255 subjects was completed in June 2015. In October 2017, we announced the presentation of positive top-line results from the SPRINT-MS Phase 2b clinical trial of MN-166 (ibudilast) in progressive MS. The trial achieved both primary endpoints of whole brain atrophy and safety and tolerability. MN-166 (ibudilast) demonstrated a statistically significant 48% reduction in the rate of progression of whole brain atrophy compared to placebo ($p=0.04$) as measured by MRI analysis using brain parenchymal fraction (BPF) and there was not an increased rate of serious adverse events in the MN-166 (ibudilast) group compared to the placebo group. In February 2018, we announced the presentation of positive clinical efficacy trends from this trial regarding the important secondary endpoint of confirmed disability progression. MN-166 (ibudilast) demonstrated a 26% reduction in the risk of confirmed disability progression compared to placebo (hazard ratio=0.74), as measured by Expanded Disability Status Scale (EDSS).

Results of the SPRINT-MS Phase 2b clinical trial of MN-166 (ibudilast) in progressive MS were published in the New England Journal of Medicine in August 2018. In April 2019, we announced results from a subgroup analysis of the SPRINT-MS Phase 2b trial of MN-166 (ibudilast) in progressive MS. The purpose of the subgroup analysis was to provide information about which types of progressive MS subjects responded best to MN-166 (ibudilast) treatment in terms of the clinically significant endpoint of the risk of confirmed disability progression compared to placebo, as measured by EDSS. The trends for reduction in the risk of confirmed disability progression were highest for the subgroup of subjects with secondary progressive MS without Relapse, in which MN-166 (ibudilast) demonstrated a 46% risk reduction compared to placebo as indicated by the hazard ratio of 0.538. Additional data from the completed SPRINT-MS Phase 2b trial of MN-166 (ibudilast) in progressive MS was presented in May 2019 at the American Academy of Neurology (AAN) 71st Annual Meeting in Philadelphia. In November 2020, we announced that positive Optical Coherence Tomography (OCT) results from the SPRINT-MS Phase 2b trial of MN-166 (ibudilast) in progressive MS were published in *Multiple Sclerosis Journal*. OCT measures included macular volume peripapillary retinal nerve fiber layer (pRNFL) thickness, and ganglion cell-inner plexiform (GCIP) layer thickness. All of these OCT measures showed less loss of retinal tissue for MN-166

(ibudilast) compared to placebo. In July 2021, we received a Notice of Allowance from the USPTO for a new patent which covers MN-166 (ibudilast) for the treatment of an ophthalmic disease/disorder or injury associated with a neurodegenerative disease/disorder or a neuro-ophthalmologic disorder. We were granted Fast Track designation from the FDA for MN-166 (ibudilast) for the treatment of progressive MS in 2016.

Amyotrophic Lateral Sclerosis: ALS, also known as Lou Gehrig's disease, is a progressive neurodegenerative disease that affects nerve cells in the brain and the spinal cord. The nerves lose the ability to trigger specific muscles, which causes the muscles to become weak. As a result, ALS affects voluntary movement and patients in the later stages of the disease may become totally paralyzed. Mean survival time of an ALS patient is two to five years. According to the ALS Association, there are at least 16,000 ALS patients in the United States and approximately 5,000 people in the United States are diagnosed with ALS each year.

We have worked with Carolinas Neuromuscular/ALS-MDA Center at Carolinas HealthCare System Neurosciences Institute, which has conducted a clinical trial of MN-166 (ibudilast) in ALS. The trial was a randomized, double-blind, placebo-controlled study which included a six-month treatment period followed by a six-month open-label extension. The study evaluated the safety and tolerability of MN-166 (ibudilast) 60 mg/day versus placebo when administered in combination with riluzole in subjects with ALS, as well as several efficacy endpoints. Subject enrollment began in October 2014. In April 2016, we announced that interim efficacy data from a mid-study analysis of the clinical trial of MN-166 (ibudilast) in ALS was presented at the AAN 68th Annual Meeting.

In December 2017, we announced positive top-line results from the ALS trial at Carolinas Neuromuscular/ALS-MDA Center. The trial achieved the primary endpoint of safety and tolerability. In addition, there was a higher rate of responders on the ALSFRS-R total score in the MN-166 (ibudilast) group compared to the placebo group. The Amyotrophic Lateral Sclerosis Functional Rating Scale-Revised (ALSFRS-R) total score measures the functional activity of an ALS subject. There was also a higher rate of responders on the ALSAQ-5 score in the MN-166 (ibudilast) group compared to the placebo group. The Amyotrophic Lateral Sclerosis Assessment Questionnaire (ALSAQ-5) score measures the physical mobility, activities of daily living and independence, eating and drinking, communication, and emotional functioning of an ALS subject. In July 2018, we announced data from ad-hoc subgroup analyses in subjects who had either bulbar onset or upper limb onset in the ALS trial at Carolinas Neuromuscular/ALS-MDA Center. In September 2018, we received feedback from the FDA regarding our clinical development plan for MN-166 (ibudilast) in ALS. In April 2019, we announced that the FDA completed its review of the protocol and determined that we may proceed with a Phase 2b/3 clinical trial of MN-166 (ibudilast) in ALS. In June 2019, we announced that a kick-off meeting for the Phase 2b/3 clinical trial of MN-166 (ibudilast) in ALS was held our headquarters in La Jolla, California. In December 2019, we announced that additional analyses of the completed clinical trial of MN-166 (ibudilast) in ALS was presented at the 30th International Symposium on ALS/MND in Perth, Australia. These analyses evaluated the potential background factors of patients' characteristics that could reasonably predict both ALS disease progression and treatment efficacy. The results of these analyses indicate that the efficacy of MN-166 (ibudilast) is expected to be more robust in patients with a short ALS history. We have incorporated the conclusions from these analyses into the design of our Phase 2b/3 clinical trial. In December 2021, we announced that a poster with an overview of our ongoing Phase 2b/3 clinical trial of MN-166 (ibudilast) in ALS was presented at the 32nd International Symposium on ALS/MND. In December 2024, a study update and interim analysis of phase 2/3 clinical data of MN-166 (ibudilast) in the COMBAT-ALS trial was presented at the 35th international symposium on ALS/MND at Montreal, Canada. Pre-defined interim analysis was conducted to evaluate the correlation between the six month and twelve month data and assessed the twelve month double blind phase trial design. Positive correlations were observed between the six month and twelve month data for CAFS Score (0.71) modified CAFS score (0.70) and ALSFRS-R (0.69). In December 2025, we announced the successful completion of patient enrollment in the COMBAT-ALS Phase 2/3

clinical trial, evaluating MN-166 (ibudilast) for the treatment of ALS. A total of 234 patients have been randomized across two treatment arms at multiple clinical sites in the United States and Canada.

In December 2015, we announced that the FDA granted Fast Track designation to MN-166 (ibudilast) for the treatment of patients with ALS. In March 2016, we announced that we received a Notice of Allowance from the USPTO for a new patent which covers MN-166 (ibudilast) for the treatment of ALS. In October 2016, we announced that the FDA granted Orphan-Drug designation to MN-166 (ibudilast) for the treatment of ALS, which will provide seven years of marketing exclusivity if it is approved for ALS. In December 2016, we announced that the European Commission granted Orphan Medicinal Product Designation for MN-166 (ibudilast) for the treatment of ALS. In January 2019, we received a Notice of Allowance from the USPTO for a new patent which covers the combination of MN-166 (ibudilast) and riluzole for the treatment of ALS and other neurodegenerative diseases.

In February 2016, we entered into an agreement to collaborate with Massachusetts General Hospital (MGH) to study the effects of MN-166 (ibudilast) on reducing brain microglial activation in ALS subjects measured by a positron emission tomography (PET) biomarker. Results of this clinical trial, which we refer to as the ALS / Biomarker study, were presented at the 30th International Symposium on ALS/MND in Perth, Australia in December 2019. In this small study, there was no detectable effect on PBR28-PET uptake or serum NFl but there was a significant reduction in serum MIF, a marker of neuroinflammation. However, because of the open-label design of this study, there was no placebo group to compare with the MN-166 (ibudilast) group, so it is not possible to draw any definitive conclusions from this study.

Degenerative Cervical Myelopathy: DCM, also known as cervical spondylotic myelopathy, involves spinal cord dysfunction from compression in the neck. DCM is the most common form of spinal cord impairment in adults and results in disability and reduced quality of life. Patients report neurological symptoms such as pain and numbness in limbs, poor coordination, imbalance, and bladder problems. According to the American Association of Neurological Surgeons, more than 200,000 cervical procedures are performed each year to relieve compression on the spinal cord or nerve roots. There are no pharmaceuticals approved for the treatment of DCM. In August 2018, we announced plans to initiate a clinical trial of MN-166 (ibudilast) in DCM in collaboration with the University of Cambridge. The trial, which is funded by a grant from the NIHR in the UK, is evaluating MN-166 (ibudilast) as an adjuvant treatment for DCM following spinal surgery to determine whether MN-166 (ibudilast) is more effective than placebo in improving outcomes after spinal surgery. The two co-primary endpoints are (1) the modified Japanese Orthopaedic Association (mJOA) Score, which evaluates motor dysfunction in upper and lower extremities, loss of sensation, and bladder sphincter dysfunction, at six months after surgery; and (2) Visual Analogue Scale (VAS) measure of neck pain at six months after surgery. In May 2019, we announced our participation at the Kick-off Meeting for this Phase 3 clinical trial in DCM, RECEDE Myelopathy in collaboration with University of Cambridge researchers. In February 2022, we announced that MN-166 (ibudilast) was discussed as a potential beneficial pharmacological agent for the treatment of DCM in *Global Spine Journal*. The publication, which was written by researchers at the University of Cambridge, discussed contemporary therapies that may hold therapeutic value and the attributes of MN-166 (ibudilast) that support its use in DCM. The publication noted that the combination of anti-inflammatory, neuroprotective, and neuroregenerative properties of MN-166 (ibudilast) leads to attenuation of glial cell activation and is the basis for the ongoing RECEDE Myelopathy trial.

Glioblastoma: According to the American Association of Neurological Surgeons, glioblastoma is an aggressive brain tumor that develops from glial cells (astrocytes and oligodendrocytes), grows rapidly, and commonly spreads into nearby brain tissue. The American Brain Tumor Association reports that glioblastomas represent about 14% of all primary brain tumors. More than 12,000 cases of glioblastoma are diagnosed each year in the U.S. According to the Glioblastoma Foundation, average life expectancy for glioblastoma patients who undergo treatment is 12 - 15 months and only four months for those who do not receive treatment. In June 2017, we announced positive results from an animal model study that examined the potential clinical efficacy of MN-166

(ibudilast) for the treatment of glioblastoma which were presented at the 2017 ASCO Annual Meeting. Results of the glioblastoma mouse model study showed that median survival was higher in the group that received combination treatment with MN-166 (ibudilast) plus temozolomide compared to the group that received temozolomide alone. In May 2018, we announced that the IND for MN-166 (ibudilast) for treatment of glioblastoma was accepted and opened with the FDA. We were also informed by the FDA that the proposed clinical investigation of MN-166 (ibudilast) in combination with temozolomide for treatment of glioblastoma may proceed. In October 2018, we announced that the FDA granted orphan-drug designation to MN-166 (ibudilast) as adjunctive therapy to temozolomide for the treatment of glioblastoma. In January 2019, we announced the initiation of enrollment in a clinical trial of MN-166 (ibudilast) in combination with temozolomide (TMZ or Temodar®) for the treatment of glioblastoma at the Dana-Farber Cancer Institute in Boston. In February 2019, we announced that *Scientific Reports* published results from the animal model study evaluating MN-166 (ibudilast) in glioblastoma. The article, "Ibudilast sensitizes glioblastoma to temozolomide by targeting MIF," is the first publication reporting the potential clinical utility of MN-166 (ibudilast) for glioblastoma. In June 2020, we announced that positive preclinical findings were published in *Frontiers in Immunology* regarding the prospect of MN-166 (ibudilast) as an adjunctive treatment for glioblastoma. The publication, entitled "Glioblastoma myeloid-derived suppressor cell subsets express differential macrophage migration inhibitory factor receptor profiles that can be targeted to reduce immune suppression", was based on our collaboration with the Cleveland Clinic. In August 2021, we announced completion of a safety review of Part 1 of the Phase 2 clinical trial of MN-166 (ibudilast) in combination with temozolomide, which enrolled 15 subjects with recurrent glioblastoma. There were no concerning safety signals observed in Part 1 and there were no serious adverse events related to MN-166 (ibudilast). Five out of 15 subjects completed cycle 6 without disease progression, i.e. 33% of subjects were progression-free at six months.

In January 2023, we announced that the Phase 2 clinical trial evaluating MN-166 (ibudilast) in combination with temozolomide in glioblastoma at the Dana-Farber Cancer Institute had completed enrollment. In February 2023, we announced the presentation of new data regarding a tumor tissue analysis from this clinical trial at the 20th Annual World Congress of SBMT. In November 2023, we announced new data and results of the Phase 2 clinical trial of MN-166 (ibudilast) in glioblastoma patients at the 28th Annual Meeting of the SNO. The primary endpoints of this Phase 2 clinical trial were safety and tolerability of MN-166 (ibudilast) and TMZ combination treatment and efficacy of the combination treatment defined as progression-free survival rate at 6 months using the RANO criteria. MN-166 (ibudilast) and TMZ combination treatment was safe and well-tolerated, and no unexpected adverse effects were reported. The trial enrolled a total of 62 patients, including 36 newly diagnosed glioblastoma patients and 26 recurrent glioblastoma patients. Progression-Free Survival at 6 months (PFS6) was 44% for newly diagnosed glioblastoma patients and 31% for recurrent glioblastoma patients. Immunohistochemistry evaluation determined that CD3 expression was a good predictor for tumor progression at five months in recurrent glioblastoma patients treated with MN-166 (ibudilast) and TMZ as patients with progression had higher CD3 tumor infiltration than patients with no progression ($p<0.05$). The presentation also included data from preclinical studies which evaluated the combination of MN-166 (ibudilast) and anti-PD1 or anti-PD-L1 therapy in glioblastoma models. In the first preclinical glioblastoma model study, median survival was 17 days for the vehicle and 28 days for the anti-PD1 inhibitor treatment alone. The addition of MN-166 (ibudilast) to the anti-PD1 inhibitor treatment significantly extended survival to a median of 66 days ($p<0.001$) for the combination therapy. In the second preclinical glioblastoma model study, median survival was 18 days for the vehicle and 26 days for the anti-PD-L1 inhibitor treatment alone. The addition of MN-166 (ibudilast) to the anti-PD-L1 inhibitor treatment significantly extended survival to a median of 34 days ($p<0.05$) for the combination therapy. We presented new data and results of a Phase 1b/2a Clinical Trial of MN-166 (ibudilast) in glioblastoma at the ASCO Annual meeting 2024 held in Chicago, IL.

In April 2022, we announced that data demonstrating that MN-166 (ibudilast) prevents metastasis in a UM animal model was published in the journal *Molecular Cancer Research*. The publication, which was written by

researchers at Columbia University Medical Center, discussed the metastatic UM mouse model study in which quantified bioluminescence signal intensity in the abdominal region was dramatically reduced by MN-166 (ibudilast) treatment ($p<0.05$). The publication also noted that histological analysis of the liver tissues of control mice showed the presence of tumor cell clusters which were not present in the liver tissues of mice treated with MN-166 (ibudilast).

Prevention of ARDS in patients with COVID-19: ARDS is a serious lung condition that causes low blood oxygen. Difficulty breathing is usually the first symptom of ARDS. Infections are the most common risk factors for ARDS and these infections may include influenza, coronavirus, or other viruses. According to the ARDS Foundation, there are an estimated 150,000 ARDS cases per year in the U.S. and the rate of death is approximately 40% for ARDS patients. In March 2020, we announced plans to initiate development of MN-166 (ibudilast) for severe pneumonia and ARDS based on positive results of a preclinical study in an animal model of ARDS (Yang et al., 2020). Results of this preclinical study showed that MN-166 (ibudilast) treatment reversed histological changes observed in the ARDS mouse model including inflammation, hemorrhage, alveolar congestion, and alveolar wall edema. Importantly, pulmonary edema was significantly reduced by MN-166 (ibudilast) treatment ($p<0.001$). In addition, MN-166 (ibudilast) significantly reduced the levels of inflammatory cytokines including TNF-alpha ($p<0.001$), IL-1beta ($p<0.001$), IL-6 ($p<0.001$), and MCP-1 ($p<0.001$) in a dose-dependent manner, indicating that ibudilast suppressed the inflammatory response. Results of this study also suggest that MN-166 (ibudilast) protects against pulmonary injury by attenuating cell apoptosis in lung tissue. In addition to data from the animal model of ARDS, MN-166 (ibudilast) has been identified as a compound with potential anti-SARS-CoV-2 activity in an in vitro study which screened 1,520 compounds for SARS-CoV-2 replication inhibition (Touret et al., 2020). In April 2020, we announced plans to initiate a clinical trial of MN-166 (ibudilast) for ARDS caused by COVID-19. In July 2020, we announced that the IND for MN-166 (ibudilast) for prevention of ARDS was accepted and opened with the FDA. We were also informed by the FDA that the proposed clinical investigation of MN-166 (ibudilast) for the prevention of ARDS in patients with COVID-19 may proceed.

In April 2022, we announced that the Phase 2 clinical trial of MN-166 (ibudilast) in hospitalized COVID-19 patients at risk for developing ARDS had completed enrollment. In June 2022, we announced positive top-line results from this Phase 2 clinical trial. MN-166 (ibudilast) demonstrated large improvements compared to placebo for all four clinical endpoints analyzed. The trial achieved statistical significance for one of the co-primary endpoints, the proportion of subjects free of respiratory failure at Day 7, with 71% of subjects in the MN-166 (ibudilast) group and 35% of subjects in the placebo group free of respiratory failure at Day 7 ($p=0.02$). For the co-primary endpoint of clinical status (i.e., improvement on NIAID scale) at Day 7, 71% of subjects in the MN-166 (ibudilast) group and 47% of subjects in the placebo group had improved clinical status at Day 7 ($p=0.08$). The trial achieved statistical significance for the proportion of subjects discharged from the hospital with 65% of subjects in the MN-166 (ibudilast) group and 29% of subjects in the placebo group discharged from the hospital at Day 7 ($p=0.02$). In addition, 0% of subjects in the MN-166 (ibudilast) group and 24% of subjects in the placebo group had worsened clinical status at Day 7 ($p=0.05$). There were two deaths in the placebo group and no deaths in the MN-166 (ibudilast) group. There were no serious adverse events related to MN-166 (ibudilast). In July 2022, we announced the initiation of a first-in-human clinical study to evaluate a new parenteral (injectable) formulation of MN-166 (ibudilast). This formulation will provide an additional option for health care providers to administer MN-166 (ibudilast) in addition to the oral formulation. In January 2023, we announced that the Phase I clinical trial of MN-166 (ibudilast) 10 mg IV infusion in healthy volunteers was completed with a favorable safety profile and was well tolerated.

MN-001 (tipelukast)

MN-001 (tipelukast) is a novel, orally bioavailable small molecule compound which exerts its effects through several mechanisms to produce its anti-fibrotic and anti-inflammatory activity in preclinical models, including leukotriene (LT) receptor antagonism, inhibition of PDEs (mainly 3 and 4), and inhibition of 5-lipoxygenase (5-LO). The 5-LO/LT pathway has been postulated as a pathogenic factor in fibrosis development and the inhibitory effect

of MN-001 (tipelukast) on 5-LO and the 5-LO/LT pathway is considered to be a novel approach to treat fibrosis. MN-001 (tipelukast) has been shown to down-regulate expression of genes that promote fibrosis including LOXL2, Collagen Type 1 and TIMP-1. MN-001 (tipelukast) has also been shown to down-regulate expression of genes that promote inflammation including CCR2 and MCP-1. In addition, histopathological data shows that MN-001 (tipelukast) reduces fibrosis in multiple animal models. We licensed MN-001 (tipelukast) from Kyorin in 2002.

Previously, we evaluated MN-001 (tipelukast) for its potential clinical efficacy in asthma and completed a Phase 2 study in asthma with positive results. MN-001 (tipelukast) has been administered to more than 600 subjects and is considered generally safe and well-tolerated.

Nonalcoholic Steatohepatitis and Nonalcoholic Fatty Liver Disease: NAFLD is a condition in which there is fat in the liver. Some individuals with NAFLD can develop NASH, a condition in which there is fat in the liver along with inflammation and damage to liver cells. NASH is a common liver disease that resembles alcoholic liver disease but occurs in people who drink little or no alcohol. According to the United States National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), NASH prevalence in adults in the United States is 1.5 - 6.5%, and approximately 24% of U.S. adults have NAFLD. The underlying cause of NASH is unclear, but it most often occurs in persons who are middle-aged and overweight or obese. Many patients with NASH have elevated serum lipids, diabetes or pre-diabetes. Progression of NASH can lead to liver cirrhosis. Liver transplantation is the only treatment for advanced cirrhosis with liver failure. At this time, there is no pharmaceutical treatment approved for NAFLD or NASH.

We completed a preclinical study evaluating the potential clinical efficacy of MN-001 (tipelukast) for the treatment of NASH. MN-001 (tipelukast) administered orally once daily (10, 30, and 100 mg/kg for three weeks) was evaluated in the STAM™ (NASH-HCC) mouse model of NASH, as measured by liver biochemistry and histopathology, NAFLD activity score (NAS), and percent of fibrosis and gene expression. MN-001 (tipelukast), in a dose-dependent manner, significantly reduced fibrosis area compared with placebo ($p<0.01$) as demonstrated by a reduction in liver hydroxyproline content, supporting the anti-fibrotic properties of MN-001 (tipelukast). MN-001 (tipelukast) significantly improved NAS ($p<0.01$). MN-001 (tipelukast), in this animal model, improved NASH pathology by inhibiting hepatocyte damage ($p<0.01$) and ballooning ($p<0.01$). At the same time, MN-001 (tipelukast) was also shown to reduce certain gene expression levels in the liver, thus implying that MN-001 (tipelukast) reduces the formation of fibrosis in the NASH model. We completed a second preclinical study that examined the potential clinical efficacy of MN-001 (tipelukast) for the treatment of advanced NASH. This study used mice in more advanced stages of NASH as compared to the first study of MN-001 (tipelukast) in a NASH mouse model. MN-001 (tipelukast) showed anti-NASH and anti-fibrotic effects in the advanced NASH mouse model. NAFLD activity score (NAS) was significantly reduced in the MN-001 (tipelukast)-treated group compared to the non-treated group ($p<0.001$). The reduction was observed consistently in all NAS components including hepatocyte ballooning score ($p<0.001$), lobular inflammation score ($p<0.01$), and steatosis score ($p<0.05$). Percent fibrosis area was also reduced in the MN-001 (tipelukast) treated group ($p<0.01$). In addition, alpha-SMA-positive staining area was significantly reduced in the MN-001 (tipelukast)-treated group ($p<0.001$). Collectively, these results provided compelling evidence that MN-001 (tipelukast) warrants further evaluation for the treatment of NASH in humans.

We have an open IND and the FDA has approved three different Phase 2 clinical trial protocols for MN-001 (tipelukast) for the treatment of NASH and NAFLD in the United States. In April 2018, we announced that we would terminate early the Phase 2 clinical trial of MN-001 (tipelukast) in NASH and NAFLD patients with hypertriglyceridemia based on the significant positive results from an interim analysis. This data was presented at the International Liver Congress 2018, the 53rd annual meeting of the European Association for the Study of the Liver (EASL) in Paris, France in April 2018. The FDA has granted Fast Track designation to MN-001 (tipelukast) for the treatment of patients with NASH with fibrosis.

In November 2020, we announced positive results of in-vitro and in-vivo studies that evaluated MN-001 (tipelukast) for its anti-liver fibrotic effect in HSCs and in an acute liver injury model at the annual meeting of the AASLD. MN-001 attenuated TGFβ1 induced HSC activation, TGFβ1 mediated increase in HSC motility and contractility, and fibrogenic signaling in a mouse acute carbon tetrachloride (CCl4)-induced liver injury model. These data provide additional scientific evidence to support MN-001's anti-fibrotic effects in the liver. In November 2021, we announced new findings from a study that investigated the mechanism by which MN-001 (tipelukast) alters triglyceride metabolism in hepatocytes at the Annual Meeting of the American Association for the Study of Liver Diseases (AASLD). This study found that MN-001 (tipelukast) had an inhibitory effect on triglyceride synthesis in HepG2 cells derived from human hepatocellular carcinoma samples. The expression of CD36, one of the fatty acid transporters involved in the uptake of arachidonic acid into liver cells, was suppressed by adding MN-001 (tipelukast). This suggests that MN-001 (tipelukast) reduces triglyceride synthesis by inhibiting arachidonic acid uptake into hepatocytes. CD36 enhances cellular fatty acid uptake in the liver and is known to be involved in the pathogenesis of fatty liver.

In April 2022, we announced that the FDA completed its review of a proposed Phase 2 clinical trial to evaluate MN-001 (tipelukast) for the treatment of patients with NAFLD, type 2 diabetes mellitus, and hypertriglyceridemia and the study may proceed. This multi-center, two-arm, randomized, double-blind, placebo-controlled Phase 2 trial will evaluate MN-001 (tipelukast) vs. placebo in approximately 40 patients in the U.S. Patients will be randomized 1:1 to receive either 500 mg/day of MN-001 (tipelukast) or placebo for 24 weeks. The co-primary endpoints are (1) change from baseline in liver fat content at Week 24, and (2) change from baseline in fasting serum triglycerides at Week 24. In July 2022, we announced the initiation of this Phase 2 clinical trial to evaluate MN-001 (tipelukast) for the treatment of patients with NAFLD, type 2 diabetes mellitus, and hypertriglyceridemia. In December 2022, we announced the presentation of positive results from a subgroup analysis of the completed Phase 2 clinical trial which evaluated MN-001 (tipelukast) in participants with NAFLD and hypertriglyceridemia (HTG) at the International Diabetes Federation (IDF) World Diabetes Congress 2022. Compared to subjects without Type 2 diabetes mellitus (T2DM), the T2DM group showed a greater reduction in serum triglyceride levels at Week 8 (50.8% reduction for with T2DM versus 17.8% reduction for without T2DM, p=0.098). Mean HDL increase was significantly greater in subjects with T2DM than subjects without T2DM at Week 8 (15.8% versus 1.0%, p<0.0002). In comparison to subjects without T2DM, the T2DM group showed a greater reduction in serum LDL levels at Week 8 (15.4% versus 6.7%). In November 2025, we announced the completion of patient enrollment in this Phase 2 clinical trial.

Table 1: MN-166 (ibudilast) Clinical Trials and Programs

Indication	Clinical Study	Institution and Funding Agency(s)	Status
Prevention of ARDS in severe COVID-19	A Randomized, Double-Blind, Placebo-Controlled, Parallel Group Study to Evaluate the Efficacy, Safety, Tolerability, Biomarkers and PK of MN-166 (Ibudilast) in COVID-19 Subjects at Risk for Developing ARDS	Multicenter MediciNova, Inc.	Completed
Primary Progressive and Secondary	A Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Safety, Tolerability and Activity of Ibudilast (MN-	Cleveland Clinic / Multicenter National Institute on Neurological Diseases and Stroke	Completed

Progressive Multiple Sclerosis	166) in Subjects with Progressive Multiple Sclerosis	MediciNova, Inc.	
Amyotrophic Lateral Sclerosis (ALS)	A Single-Center, Randomized, Double-Blind, Placebo-Controlled, Six Month Clinical Trial Followed by an Open-Label Extension to Evaluate the Safety, Tolerability, and Clinical Endpoint Responsiveness of Ibudilast (MN-166) in Subjects with Amyotrophic Lateral Sclerosis (ALS)	Carolinas HealthCare System Neurosciences Institute MediciNova, Inc.	Completed
ALS / Biomarker	A Biomarker Study to Evaluate MN-166 (ibudilast) in Subjects with Amyotrophic Literal Sclerosis (ALS)	Massachusetts General Hospital MediciNova, Inc.	Completed
Amyotrophic Lateral Sclerosis (ALS)	A Phase 2b/3, Multi-Center, Randomized, Double-Blind, Placebo-Controlled, 12 Month Clinical Trial to Evaluate the Efficacy and Safety of MN-166 (ibudilast) Followed by an Open-Label Extension in Subjects with Amyotrophic Lateral Sclerosis	Multicenter MediciNova, Inc.	Enrollment Completed
Degenerative Cervical Myelopathy	A multi-centre, double-blind, randomized, placebo-controlled trial assessing the efficacy of Ibudilast as an adjuvant treatment to decompressive surgery for degenerative cervical myelopathy	University of Cambridge / Multicenter National Institute for Health Research (NIHR) in the U.K.	Ongoing

Sales and Marketing

We currently have no marketing and sales capabilities and we expect to rely on strategic partners to commercialize our products.

Manufacturing

We rely on third parties to manufacture bulk active pharmaceutical ingredients (API) and finished investigational products for research, development, preclinical and clinical trials. We expect to continue to rely on third party manufacturers for the manufacture of the API and finished products for our clinical and any future commercial production requirements. We believe that there are several manufacturing sources available at commercially reasonable terms to meet our clinical requirements and any future commercial production requirements for the API of our products and the finished drug products.

For the MN-166 (ibudilast) development program, we have historically sourced and imported delayed-release ibudilast capsules, marketed in Japan as Pinatos®, from Taisho Pharmaceutical Co., Ltd. (Taisho). In addition, we use contract manufacturers to manufacture API and finished product for the MN-166 (ibudilast) development program.

Intellectual Property and License Agreements

Since our inception in September 2000, we have entered into license agreements with pharmaceutical companies which cover our current product candidates. We have also entered into license agreements with universities which cover additional intellectual property related to our product candidates. In general, we seek to procure patent protection for our anticipated products, or obtain such protection from the relevant patents owned by our licensors. We hold 40 issued U.S. patents and have filed 5 additional U.S. patent applications. We also hold more than 130 issued foreign patents and more than 30 pending foreign patent applications corresponding to these U.S. patents and patent applications. We are not aware of any third party infringement of the patents owned or licensed by us and are not party to any material claims by third parties of infringement by us of such third parties' intellectual property rights. The following is a description of our existing license agreements and intellectual property rights for each of our clinical product candidates.

General

Our proposed commercial activities may conflict with patents which have been or may be granted to competitors, universities and/or others. Third parties could bring legal action against us, our licensors or our sub-licensees claiming patent infringement and could seek damages or enjoin manufacturing and marketing of the affected product or its use or the use of a process for the manufacturing of such products. If any such actions were to be successful, in addition to any potential liability for indemnification, damages and attorneys' fees in certain cases, we could be required to obtain a license, which may not be available on commercially reasonable terms or at all, in order to continue to manufacture, use or market the affected product. We also rely upon unpatented proprietary technology because, in some cases, our interests would be better served by reliance on trade secrets or confidentiality agreements than by patents. However, others may independently develop substantially equivalent proprietary information and techniques or gain access to or disclose such proprietary technology. We may not be able to meaningfully protect our rights in such unpatented proprietary technology. We may also conduct research on other pharmaceutical compounds or technologies, the rights to which may be held by, or be subject to patent rights of, third parties. Accordingly, if products based on such research are commercialized, such commercial activities may infringe patents or other rights, which may require us to obtain a license to such patents or other rights. We are not aware of any third party infringements of patents we hold or have licensed and have not received any material claims by third parties of infringement by us of such parties' intellectual property rights.

There can be no assurance that patent applications filed by us or others, in which we have an interest as assignee, licensee or prospective licensee, will result in patents being issued or that, if issued, any of such patents will afford protection against competitors with similar technology or products or could not be circumvented or challenged. For example, we have U.S. patents covering the method of treating progressive MS with MN-166 (ibudilast), the method of treating ALS with MN-166 (ibudilast), the method of treating glioblastoma with MN-166 (ibudilast) as part of a combination therapy, the method of treating drug addiction or drug dependence with MN-166 (ibudilast), and the method of treating neuropathic pain with MN-166 (ibudilast), but we do not have any composition of matter patent claims for MN-166 (ibudilast) because that patent has expired. As a result, unrelated third parties may develop products with the same API as MN-166 (ibudilast) so long as such parties do not infringe our method of use patents, other patents we have exclusive rights to through our licensors or any patents we may obtain for MN-166 (ibudilast).

In addition, if we develop certain products that are not covered by any patents, we will be dependent on obtaining market exclusivity under the new chemical entity exclusivity provisions of the Hatch-Waxman Act for such products in the United States and/or data exclusivity provisions in Europe. If we are unable to obtain strong proprietary protection for our products after obtaining regulatory approval, competitors may be able to market competing generic products by taking advantage of an abbreviated procedure for obtaining regulatory clearance, including the ability to demonstrate bioequivalency to our product(s) without being required to conduct lengthy clinical trials. Certain of our license agreements provide for reduced or foregone royalties in the event of generic competition.

MN-166 (ibudilast)

On October 22, 2004, we entered into an exclusive license agreement with Kyorin for the development and commercialization of MN-166 (ibudilast). Kyorin is a fully integrated Japanese pharmaceutical company and is listed on the Tokyo Stock Exchange. We obtained an exclusive, worldwide (excluding Japan, China, South Korea and Taiwan), sub-licensable license to the patent rights related to MN-166 (ibudilast) for the treatment of MS, except for ophthalmic solution formulations. MN-166 (ibudilast) is not covered by a composition of matter patent. The United States method of use patent for MN-166 (ibudilast) in MS underlying the license expired on August 10, 2018. Corresponding method of use patents in certain foreign countries also expired on August 10, 2018. Under the terms of the agreement, we granted to Kyorin an exclusive, royalty-free, sub-licensable license to use the preclinical, clinical and regulatory databases to develop ophthalmic products incorporating the MN-166 (ibudilast) compound anywhere in the world and non-ophthalmic products incorporating the MN-166 (ibudilast) compound outside of our territory.

The license agreement may be terminated by either party following an uncured breach of any material provision in the agreement by the other party. We may terminate the agreement for any reason with 90 days' written notice to Kyorin or, in the event that a third party claims that MN-166 (ibudilast) infringes upon such third party's intellectual property rights, with 30 days' written notice.

The term of this agreement is determined on a country-by-country basis and extends until the later of the expiration of the obligation to make payments under the agreement or the last date on which the manufacture, use or sale of the product would infringe a valid patent claim held by Kyorin but for the license granted by the agreement or the last date of the applicable market exclusivity period. In the absence of a valid patent claim and generic competition in a particular country, the agreement will expire on the earlier of five years from the date of the first commercial sale of the product by us or the end of the second consecutive calendar quarter in which generic competition exists in such country.

Under the license agreement, we have paid Kyorin $700,000 to date, and we are obligated to make payments of up to $5.0 million based on the achievement of certain clinical and regulatory milestones. We are also obligated to pay a royalty on net sales of the licensed products.

We own, co-own or hold licenses to 22 issued U.S. patents and 5 pending U.S. patent applications as well as more than 50 issued foreign patents and more than 25 pending foreign patent applications covering MN-166 (ibudilast) and its analogs. These patents and patent applications are related to our development portfolio and are primarily directed to methods of treating various indications using MN-166 (ibudilast) and its analogs.

We have been granted a U.S. patent which covers the use of MN-166 (ibudilast) for the treatment of progressive forms of MS. This patent will expire no earlier than November 2029, not including a potential extension under patent term restoration rules, and covers a method of treating PPMS or SPMS by administering MN-166 (ibudilast). Counterparts of this patent application have been granted in certain foreign jurisdictions. We have been granted a U.S. patent which covers the combination of MN-166 (ibudilast) and interferon-beta for the treatment of progressive MS, including both PPMS and SPMS, and it expires no earlier than October 2039. We have been

granted a U.S. patent which covers the use of MN-166 (ibudilast) for the treatment of amyotrophic lateral sclerosis (ALS) and it expires no earlier than January 2029. We have been granted a U.S. patent which covers the combination of MN-166 (ibudilast) and riluzole for the treatment of ALS and other neurodegenerative diseases and it expires no earlier than November 2035. Counterparts of this patent application have been granted in certain foreign jurisdictions. We have been granted two U.S. patents which cover the use of MN-166 (ibudilast) as part of a combination treatment for glioblastoma and these patents expire no earlier than February 2039. We have been granted a U.S. patent which covers the use of MN-166 (ibudilast) for the treatment of drug addiction or drug dependence or withdrawal syndrome and it expires no earlier than January 2030. Counterparts of this patent application have been granted in certain foreign jurisdictions. We have been granted a U.S. patent which covers the use of MN-166 (ibudilast) for the treatment of an ophthalmic disease/disorder or injury associated with a neurodegenerative disease/disorder or a neuro-ophthalmologic disorder and it expires no earlier than October 2039.

MN-001 (tipelukast)

On March 14, 2002, we entered into an exclusive license agreement with Kyorin for the development and commercialization of MN-001 (tipelukast). We obtained an exclusive, worldwide (excluding Japan, China, South Korea and Taiwan) sub-licensable license to the patent rights and know-how related to MN-001 (tipelukast) disclosed and included in, or covered by, these patents, in all indications, except for ophthalmic solution formulations. This license included an exclusive, sub-licensable license under two U.S. patents and certain corresponding patents in foreign countries. The United States composition of matter patent for MN-001 (tipelukast) underlying the license expired on February 23, 2009. Foreign composition of matter patents for MN-001 (tipelukast) has also expired. We own 15 issued U.S. patents and 65 foreign patents covering certain compositions, uses and manufacturing processes associated with MN-001 (tipelukast). Uses covered by these U.S. patents include nonalcoholic steatohepatitis (NASH), advanced NASH with fibrosis, nonalcoholic fatty liver disease (NAFLD), steatosis, hypertriglyceridemia, hypercholesterolemia, hyperlipoproteinemia, fibrosis, ulcerative colitis, interstitial cystitis, and irritable bowel syndrome. Patent applications corresponding to these U.S. patents have been filed in certain foreign countries and some of the foreign patents have issued.

Under the terms of the agreement, we granted to Kyorin an exclusive, royalty-free, sub-licensable license to use the preclinical, clinical and regulatory databases to develop ophthalmic products incorporating MN-001 (tipelukast) anywhere in the world and non-ophthalmic products incorporating MN-001 (tipelukast) outside of our territory. The license agreement may be terminated by either party following an uncured breach of any material provision in the agreement by the other party, and we may terminate the agreement for any reason with 90 days' written notice to Kyorin or, in the event that a third party claims that the licensed patent rights or know-how infringe upon such third party's intellectual property rights, with 30 days' written notice.

The term of this agreement is determined on a country-by-country basis and extends until the later of the expiration of the obligation to make payments under the agreement or the last date on which the manufacture, use or sale of the product would infringe a valid patent claim held by Kyorin but for the license granted by the agreement or the last date of the applicable market exclusivity period. In the absence of a valid patent claim and generic competition in a particular country, the agreement will expire on the earlier of five years from the date of the first commercial sale of the product by us or the end of the second consecutive calendar quarter in which generic competition exists in such country.

Under the license agreement, we have paid Kyorin $4.0 million to date, and we are obligated to make payments of up to $5.0 million based on the achievement of clinical and regulatory milestones. We are also obligated to pay a royalty on net sales of the licensed products.

Competition

The development and commercialization of new drugs is extremely competitive and characterized by extensive research efforts and rapid technological progress. Competition in our industry occurs on a variety of fronts, including developing and bringing new products to market before others, developing new products to provide the same benefits as existing products at lower cost and developing new products to provide benefits superior to those of existing products. We face competition from pharmaceutical and biotechnology companies, as well as numerous academic and research institutions and governmental agencies in the United States and abroad. Some of these competitors have products or are pursuing the development of drugs that target the same diseases and conditions that are the focus of our product development programs. Many of our competitors have products that have been approved or are in advanced development and may succeed in developing drugs that are more effective, safer, more affordable, or more easily administered than ours or that achieve patent protection or commercialization sooner than our products. Our competitors may also develop alternative therapies that could further limit the market for any products that we are able to obtain approval for, if at all.

In many of our target disease areas, potential competitors are working to develop new compounds with different mechanisms of action and attractive efficacy and safety profiles. Many of our competitors have substantially greater financial, research and development resources (including personnel and technology), clinical trial experience, manufacturing, sales and marketing capabilities and production facilities than we do. Smaller companies also may prove to be significant competitors, particularly through proprietary research discoveries and collaboration arrangements with large pharmaceutical and established biotechnology companies.

MN-166 (ibudilast) for Progressive Multiple Sclerosis (Progressive MS)

Our MN-166 (ibudilast) product candidate is in development for the treatment of progressive MS. Mitoxantrone is approved for the treatment of secondary progressive MS but it cannot be used on a long-term basis because of the potential for cardiac toxicity. There are numerous drugs approved for the treatment of secondary progressive MS with relapses (also known as active secondary progressive MS) including Mayzent (siponimod), Mavenclad (cladribine), Vumerity (diroximel fumarate), Zeposia (ozanimod), Kesimpta (ofatumumab), Bafiertam (monomethyl fumarate), Ponvory (ponesimod), Briumvi (ublituximab-xiiy), Avonex (interferon beta-1a), Betaseron (interferon beta-1b), Rebif (interferon beta-1a), Extavia (interferon beta-1b), Plegridy (peginterferon beta-1a), Copaxone (glatiramer acetate), Glatopa (glatiramer acetate), Gilenya (fingolimod), Aubagio (teriflunomide), Tascenso ODT (fingolimod), Tecfidera (dimethyl fumarate), Lemtrada (alemtuzumab), Tysabri (natalizumab) and Tyruko (natalizumab-sztn). Ocrevus (ocrelizumab) is approved for the treatment of primary progressive MS and secondary progressive MS with relapses. There are no drugs specifically approved for the treatment of secondary progressive MS without relapses. Other programs in clinical development for progressive MS include Sanofi's tolebrutinib, Roche's fenebrutinib, and AB Science's masitinib.

MN-166 (ibudilast) for Amyotrophic Lateral Sclerosis (ALS)

Generic riluzole, which is also sold under the brand names Rilutek and Tiglutik, Radicava (edaravone), Relyvrio (sodium phenylbutyrate and taurursodiol), and Qalsody (tofersen) are approved for the treatment of ALS. We are aware of additional compounds in clinical development for the treatment of ALS at other companies including BrainStorm Cell Therapeutics, AB Science, Ionis Pharmaceuticals, and Clene.

MN-166 (ibudilast) for Degenerative Cervical Myelopathy

There are no pharmaceuticals currently approved for the treatment of degenerative cervical myelopathy.

MN-166 (ibudilast) for Glioblastoma

Surgery, radiation, and chemotherapy with the drug temozolomide is the current standard of treatment for glioblastoma. GLIADEL® WAFER (carmustine implant) and AVASTIN® (bevacizumab) are also approved for the treatment for glioblastoma. We are aware of additional compounds in development for the treatment of

glioblastoma at other companies including Kazia Therapeutics, Kintara Therapeutics, Denovo Biopharma, Laminar Pharmaceuticals, and TVAX Biomedical.

MN-166 (ibudilast) for Prevention of ARDS in patients with COVID-19

While we are not aware of any other therapeutics that are in development specifically for this indication, we are aware of other therapeutics approved or in development for the treatment COVID-19. In October 2020, Gilead Sciences announced FDA approval of its antiviral drug Veklury (remdesivir) for the treatment of patients with COVID-19 requiring hospitalization. In November 2020, the FDA granted Emergency Use Authorization (EUA) for Eli Lilly's investigational neutralizing antibody bamlanivimab (LY-CoV555) for the treatment of COVID-19 patients at high risk for progressing to severe COVID-19 and/or hospitalization. In November 2020, Eli Lilly and Incyte announced that the FDA issued an EUA for the distribution and emergency use of baricitinib to be used in combination with remdesivir in hospitalized COVID-19 patients. In November 2020, Regeneron Pharmaceuticals announced that its multi-antibody therapy casirivimab and imdevimab administered together received EUA from the FDA for the treatment of COVID-19. In February 2021, the FDA issued an EUA for Eli Lilly's bamlanivimab and etesevimab, administered together, for the treatment of COVID-19 patients who are at high risk for progression to severe COVID-19. In May 2021, the FDA issued an EUA for GlaxoSmithKline's sotrovimab for the treatment of COVID-19 patients who are at high risk for progression to severe COVID-19. In June 2021, the FDA issued an EUA for Roche's Actemra (tocilizumab) for the treatment of hospitalized COVID-19 patients. In December 2021, Pfizer announced that the FDA granted an EUA for PAXLOVID (nirmatrelvir tablets and ritonavir tablets) for the treatment of mild to moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) who are at high risk for progression to severe COVID-19. In December 2021, Merck and Ridgeback Biotherapeutics announced that the FDA granted an EUA for molnupiravir, an investigational oral antiviral, to treat mild to moderate COVID-19 in adults who are at high risk for progression to severe COVID-19 and for whom alternative COVID-19 treatment options authorized by the FDA are not accessible or clinically appropriate. In February 2022, the FDA issued an EUA for Eli Lilly's bebtelovimab for the treatment of mild to moderate COVID-19 in adults and pediatric patients who are at high risk for progression to severe COVID-19 and for whom alternative COVID-19 treatment options are not accessible or clinically appropriate. In November 2022, the FDA issued an EUA for Swedish Orphan Biovitrum's Kineret (anakinra) for the treatment of hospitalized COVID-19 adults with pneumonia requiring supplemental oxygen who are at risk for progressing to severe respiratory failure and are likely to have an elevated plasma soluble urokinase plasminogen activator receptor (suPAR). In April 2023, the FDA issued an EUA for InflaRx's Gohibic (vilobelimab) for the treatment of COVID-19 in hospitalized adults when initiated within 48 hours of receiving invasive mechanical ventilation or extracorporeal membrane oxygenation (artificial life support). We are aware of additional treatments in development for the treatment of COVID-19 at other companies including Merck, AstraZeneca, Gilead Sciences, and Rigel Pharmaceuticals.

MN-001 (tipelukast) for Nonalcoholic Steatohepatitis (NASH) and Nonalcoholic Fatty Liver Disease (NAFLD)

There is currently one pharmaceutical approved for the treatment of NASH or NAFLD, which is Rezdiffera developed by Madrigal Pharmaceuticals. We are aware of compounds in clinical development for the treatment of NASH or NAFLD at other companies including Galectin Therapeutics, Gilead Sciences, Galmed Pharmaceuticals, Pfizer, Novo Nordisk, and Merck.

Government Regulation

Government authorities in the United States and other countries extensively regulate the research, development, testing, manufacture, labeling, promotion, advertising, distribution, sampling, marketing and import and export of pharmaceutical products and biologics such as those we are developing. In the United States, the FDA, under the Federal Food, Drug and Cosmetic Act, as amended, and other federal statutes and regulations, subjects pharmaceutical products to extensive and rigorous review. Any failure to comply with applicable requirements, both before and after approval, may subject us, our third party manufacturers, contractors, suppliers and partners to administrative and judicial sanctions, such as a delay in approving or refusal to approve pending applications, fines, warning letters, product recalls, product seizures, total or partial suspension of manufacturing or marketing, injunctions and/or criminal prosecution.

United States Regulatory Approval

Overview. In the United States, drugs and drug testing are regulated by the FDA under the Federal Food, Drug and Cosmetic Act (FDCA) as well as state and local government authorities. All our product candidates in development will require regulatory approval by government agencies prior to commercialization. To obtain approval of a new product from the FDA, we must, among other requirements, submit data supporting safety and efficacy, as well as detailed information on the manufacture and composition of the product and proposed labeling. Our product candidates are in the early stages of testing and none has been approved. The steps required before a drug can be approved generally involve the following:

- completion of nonclinical laboratory, animal studies, and formulation studies;
- submission of an IND application which must become effective before human clinical trials may begin in the United States;
- completion of adequate and well-controlled human clinical trials to establish the safety and efficacy of the product candidate for each indication for which approval is sought;
- submission to the FDA of a New Drug Application (NDA) accompanied by a substantial user fee;
- development of manufacturing processes which conform to FDA-mandated commercial good manufacturing practices (cGMPs) and satisfactory completion of FDA inspections to assess cGMP compliance and clinical investigator compliance with good clinical practices; and
- FDA review and approval of an NDA, which process may involve input from advisory committees to the FDA and may include post-approval commitments for further clinical studies and distribution restrictions intended to mitigate drug risks.

The testing, collection of data, preparation of necessary applications and approval process requires substantial time, effort and financial resources. Additionally, statutes, rules, regulations and policies may change and new regulations may be issued that could delay approvals of our drugs. The FDA may not act quickly or favorably in reviewing our applications, and we may encounter significant difficulties and costs in our efforts to obtain FDA approvals that could delay or preclude us from marketing our product candidates.

Preclinical Tests. Preclinical tests include laboratory evaluation of the product candidate, its chemistry, toxicity, formulation and stability, as well as animal studies to assess the potential safety and efficacy of the product candidate. The results of the preclinical tests, together with manufacturing information, analytical data and other available information about the product candidate, are submitted to the FDA as part of an IND. Preclinical tests and studies can take several years to complete and, despite completion of those tests and studies, the FDA may not permit clinical testing to begin.

The IND Process. An IND must be effective to administer an investigational drug to humans. The IND will automatically become effective 30 days after its receipt by the FDA unless the FDA, before that time, places the IND on clinical hold. At any time thereafter, the FDA may raise concerns or questions about the conduct of the trials as outlined in the IND and impose a clinical hold if the FDA deems it appropriate. In such case, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can begin or continue. The IND application process may become extremely costly and substantially delay development of our product candidates. Moreover, positive results in preclinical tests or prior human studies do not necessarily predict positive results in subsequent clinical trials.

Annual progress reports detailing the results of the clinical trials must be submitted to the FDA and written IND safety reports must be promptly submitted to the FDA and the investigators for serious and unexpected adverse events or any findings from tests in laboratory animals that suggest a significant risk for human subjects.

Clinical Trials. Human clinical trials are typically conducted in three sequential phases that may overlap:

- Phase 1: The drug candidate is initially introduced into a small number of healthy human subjects or patients and tested for safety, dosage tolerance, absorption, distribution, excretion and metabolism. If the investigational product is considered too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in the target population.

- Phase 2: The drug candidate is introduced into a limited patient population to assess the efficacy of the drug in specific, targeted indications, assess dosage tolerance and optimal dosage, and to identify possible adverse effects and safety risks.

- Phase 3: The drug candidate is introduced into an expanded patient population at geographically dispersed clinical trial sites to further evaluate clinical efficacy and safety. The purpose of the Phase 3 trial is to conduct a risk/benefit analysis of the potential drug and provide an adequate basis for product labeling. It is common to have two adequate and well-controlled Phase 3 trials for the FDA to approve an NDA.

Prior to initiation of each clinical trial, an independent Institutional Review Board (IRB) for each medical site proposing to conduct the clinical trials must review and approve the study protocol and study subjects must provide informed consent for participation in the study.

We cannot be certain that we will successfully complete Phase 1, 2 or 3 testing of our drug candidates within any specific time period, if at all. Clinical trials must be conducted in accordance with the FDA's good clinical practices (GCP) requirements. The FDA may order the partial, temporary or permanent discontinuation of a clinical trial at any time or impose other sanctions if it believes that the clinical trial is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. The IRB may also require the clinical trial at that site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions. In addition, we may suspend or discontinue a clinical trial at any time for a variety of reasons, including a finding that the research subjects or patients are being exposed to an unacceptable health risk.

During the development of a new drug, we may request to meet with the FDA at times such as prior to submitting an IND, at the End-of-Phase 2 meeting, and before an NDA is submitted, and meetings are not limited to these certain times. The purpose of the End-of-Phase 2 meeting is to discuss the Phase 2 clinical trial results and present plans for a pivotal Phase 3 trial that, in our opinion, will support the approval of the new drug. Additional animal safety studies, formulation studies and pharmacology studies are concurrently conducted with the ongoing clinical trials. Also, in compliance with cGMP requirements, the process for manufacturing commercial quantities of the new drug is finalized, with the expectation that the quality, purity, and potency of the drug will meet standards. A sponsor may also request a Special Protocol Assessment (SPA), the purpose of which is to reach

agreement with the FDA on the Phase 3 clinical trial protocol design and analysis that will form the primary basis of an efficacy claim.

Fast Track Designation: The FDA has a Fast Track program that is intended to expedite or facilitate the process for reviewing new drugs and biological products that meet certain criteria. Specifically, new drugs and biological products are eligible for Fast Track designation if they are intended to treat a serious or life-threatening condition and demonstrate the potential to address unmet medical needs for the condition. Fast Track designation applies to the combination of the product and the specific indication for which it is being studied. Unique to a Fast Track product, the FDA may consider for review sections of the NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA.

Any product submitted to the FDA for marketing, including a Fast Track program, may also be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. Any product is eligible for priority review if it has the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or a significant improvement in the treatment, diagnosis or prevention of a disease compared to marketed products. 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. Additionally, a product may be eligible for accelerated approval. Drug products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval, which means that they may be approved on the basis of adequate and well-controlled clinical trials establishing that the product has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit, or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity. As a condition of approval, the FDA may require that a sponsor of a drug product receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product. Fast Track designation, priority review and accelerated approval do not change the standards for approval but may expedite the development or approval process.

United States Patent Term Restoration and Marketing Exclusivity: Depending upon the timing, duration and specifics of the FDA approval of a drug candidate, some U.S. patents covering the product candidates may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of an NDA plus the time between the submission date of an NDA and the approval of that application. Only one patent applicable to an approved drug is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may apply for restoration of patent terms for one or more of our currently owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant NDA.

Market exclusivity provisions under the FDCA can also delay the submission or the approval of certain applications of other companies seeking to reference another company's NDA. The FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to obtain approval of an

NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application (ANDA) or a 505(b)(2) NDA submitted by another company for another version of such drug 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 also provides three years of marketing exclusivity for an NDA, or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the conditions associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the original active agent. 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 the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness. Pediatric exclusivity is another type of regulatory market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric trial in accordance with an FDA-issued "Written Request" for such a trial.

Regulation Outside the United States: In addition to regulations in the United States, we and our strategic alliance partners will be subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our products.

Whether or not we obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the United States have a similar process that requires the submission of a clinical trial application much like the IND prior to the commencement of human clinical trials. In the European Union, for example, a clinical trial application (CTA) must be submitted to each country's national health authority and an independent ethics committee, much like the FDA and IRB, respectively. Once the CTA is approved in accordance with a country's requirements, clinical trial development may proceed.

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

To obtain regulatory approval of an investigational drug under European Union regulatory systems, we or our strategic alliance partners must submit a marketing authorization application. The application used to file the NDA in the United States is similar to that required in the European Union, except for, among other things, country-specific document requirements.

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

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

Human Capital Resources

We have assembled an experienced and cohesive management and support team, with core competencies in general management, clinical development, regulatory affairs and corporate development. We have six employees as of the date of this report, all of which are full-time. We believe that our relations with our employees are good, and we have no history of work stoppages.

Company Information

We were originally incorporated in the State of Delaware in September 2000. Our principal executive offices are located at 4275 Executive Square, Suite 300, La Jolla, CA 92037. Our telephone number is 858-373-1500. Our website is www.medicinova.com, which includes links to reports we have filed with the Securities and Exchange Commission (SEC). The information contained in, or that can be accessed through, our website is not part of, and is not incorporated into, this Annual Report on Form 10-K.

Item 1A. Risk Factors

We operate in a dynamic and rapidly changing environment that involves numerous risks and uncertainties. Certain factors may have a material adverse effect on our business, financial condition and results of operations, and you should carefully consider them. Accordingly, in evaluating our business, we encourage you to consider the following discussion of risk factors, in its entirety, in addition to other information contained in this Annual Report on Form 10-K and our other public filings with the Securities and Exchange Commission (SEC). Other events that we do not currently anticipate or that we currently deem immaterial may also affect our results of operations and financial condition.

Risks Related to Our Business and Industry

We have incurred significant operating losses since our inception and expect that we will incur continued losses for the foreseeable future.

We have incurred significant net losses since our inception in September 2000. For the years ended December 31, 2025 and 2024, we had a net loss of $12.0 million and $11 million, respectively. As of December 31, 2025 and December 31, 2024, our accumulated deficit was $438.7 million and $426.8 million, respectively. We expect to incur substantial net losses for the next several years as we continue to develop certain of our existing product candidates, and over the long-term if we expand our research and development programs and acquire or in-license products, technologies or businesses that are complementary to our own. Additionally, the net losses we incur may fluctuate significantly from quarter to quarter such that a period-to-period comparison of our results of operations may not be a good indicator of our future performance. As of December 31, 2025, we had available cash and cash equivalents of $30.8 million and working capital of $27.2 million. There can be no assurances that there will be adequate financing available to us in the future on acceptable terms, or at all. If we are unable to obtain additional financing, we may have to out-license or sell one or more of our programs or cease operations.

Our future cash requirements will also depend on many factors, including:

- progress in, and the costs of future planned clinical trials and other research and development activities;
- the scope, prioritization and number of our product development programs;
- our obligations under our license agreements, pursuant to which we may be required to make future milestone payments upon the achievement of various milestones related to clinical, regulatory or commercial events;
- our ability to establish and maintain strategic collaborations, including licensing agreements and other arrangements;
- the time and costs involved in obtaining regulatory approvals;

- the costs of securing manufacturing arrangements for clinical or commercial production of our product candidates;
- the costs associated with any expansion of our management, personnel, systems and facilities;
- the costs associated with any litigation;
- the costs associated with the operations or wind-down of any business we may acquire;
- inflation and rapid increases in interest rates;
- the costs involved in filing, prosecuting, enforcing and defending patent claims and other intellectual property rights; and
- the costs of establishing or contracting for sales and marketing capabilities and commercialization activities if we obtain regulatory approval to market our product candidates.

We expect our research and development expenses to increase moderately in 2026 relative to 2025 as we continue development of MN-166 (ibudilast), MN-001 (tipelukast), and any other future product candidates. We do expect to continue to incur significant operating losses for the foreseeable future. Because of the numerous risks and uncertainties associated with developing drug products, we are unable to predict the extent of any future losses or when we will become profitable, if at all.

If we have taxable income in the future, utilization of the net operating losses (NOL) and tax credit carryforwards will be subject to a substantial annual limitation under Sections 382 and 383 of the Internal Revenue Code of 1986, and similar state provisions due to ownership change limitations that have occurred, which will limit the amount of NOL and tax credit carryforwards that can be utilized to offset future taxable income and tax, respectively. We have conducted a study and determined that, through December 31, 2023, no ownership changes have occurred. There is a risk that additional changes in ownership have occurred since the completion of our analysis. If a requisite ownership change occurs, the amount of remaining tax attribute carryforwards available to offset taxable income and reduce income tax expense in future years may be restricted or eliminated. Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. As a result, even if we attain profitability, we may be unable to use a material portion of our NOLs and other tax attributes, which could adversely affect our future cash flows.

We will need to obtain additional funding to complete the development and any commercialization of our product candidates, if approved. If we fail to obtain this capital necessary to fund our operations, we will be forced to significantly delay, scale back or eliminate some or all of our clinical or regulatory activities or other operations.

We have consumed substantial amounts of capital since our inception in September 2000.

As of the date of this report, we believe we have sufficient working capital to fund operations at least through the next twelve months following the filing of this Annual Report on Form 10-K. Our business will continue to require us to incur substantial research and development expenses. We believe that without raising additional capital from accessible sources of financing, we will not otherwise have adequate funding to continue our operations and to complete the development of our existing product candidates or the commercialization of any products we successfully develop. There is no guarantee that adequate funds will be available when needed from debt or equity financings, arrangements with partners, or from other sources, on terms attractive to us, or at all. The inability to obtain sufficient additional funds when needed to fund our operations would require us to significantly delay, scale back, or eliminate some or all of our clinical or regulatory activities and reduce general and administrative expenses.

We do not have any products that are approved for commercial sale and therefore currently generate no revenues from sales of any products and may never generate any revenues from product sales or be profitable in the foreseeable future, if ever.

To date, we have funded our operations primarily from sales of our securities and, to a lesser extent, debt financing. We do not have any products that are approved for commercial sale and do not anticipate generating any product revenue unless and until one of our product candidates receives the regulatory approvals necessary for commercialization in one or more jurisdictions. We do not expect to receive any revenues from the commercialization of our product candidates for the next several years, if at all. We anticipate that, prior to our commercialization of a product candidate, out-licensing upfront and milestone payments will be our primary source of revenue if we can enter into collaborations, strategic alliances or other agreements that would provide us with such revenues. To obtain revenues from sales of our product candidates, we must succeed, either alone or with third parties, in developing, obtaining regulatory approval for, manufacturing and marketing drugs with commercial potential. We may never succeed in these activities, and we may not generate sufficient revenues to continue our business operations or achieve and maintain profitability.

We are largely dependent on the success of our MN-166 (ibudilast) and MN-001 (tipelukast) product candidates and we cannot be certain that these product candidates will receive regulatory approval or be successfully commercialized.

We currently have no products that are approved for commercial sale and we have never had any products approved for commercial sale. We cannot guarantee that we will ever have any drug products approved for sale. The research, testing, manufacturing, labeling, approval, sales, marketing and distribution of drug products are subject to extensive regulation by the Food and Drug Administration (FDA) and comparable regulatory authorities in other countries. We are not permitted to market any of our product candidates in the United States or other jurisdictions until we submit and receive approval of a New Drug Application (NDA) for a product candidate from the FDA or its foreign equivalent from a foreign regulatory authority, as applicable. Obtaining FDA approval is a lengthy, expensive and uncertain process. To date we have invested a substantial majority of our business efforts and financial resources in the development and commercialization of our MN-166 (ibudilast) and MN-001 (tipelukast) product candidates. Our future success is dependent on our ability to successfully develop, obtain regulatory approval for, and commercialize MN-166 (ibudilast) and MN-001 (tipelukast) and we cannot accurately predict when or if either MN-166 (ibudilast) or MN-001 (tipelukast) will receive regulatory approval. Neither of these product candidates have completed the clinical development process, and therefore we have not submitted an NDA or foreign equivalent or received marketing approval for either product candidate.

The clinical development program for our product candidates may not lead to commercial products for a number of reasons, including our clinical trials' failure to demonstrate to the FDA's satisfaction that the product candidate is safe and effective, or our failure to obtain necessary approvals from the FDA or similar foreign regulatory authorities for any reason. We may also fail to obtain the necessary approvals if we have inadequate financial or other resources to advance our product candidates through the clinical trial process or are unable to secure a strategic collaboration or partnership with a third party. Any failure or delay in completing clinical trials or obtaining regulatory approval for our product candidates in a timely manner would have a material and adverse impact on our business and our stock price.

Because the results of early clinical trials are not necessarily predictive of future results, our product candidates we advance into clinical trials in any indication may not have favorable results in later clinical trials, if any, or receive regulatory approval.

Our product candidates are subject to the risks of failure inherent in drug development. We will be required to demonstrate through well-controlled clinical trials that our product candidates are safe and effective for use in a diverse population for the relevant target indications before we can seek regulatory approvals for their commercial sale. Success in early clinical trials does not mean that later clinical trials will be successful because product candidates in later-stage clinical trials may fail to demonstrate sufficient safety or efficacy despite having progressed through initial clinical testing, even at statistically significant levels. Clinical trial failure may result from a multitude of factors including flaws in trial design, dose selection, placebo effect, patient enrollment criteria, relatively smaller sample size in earlier trials, and failure to demonstrate favorable safety or efficacy traits. As such, failure in clinical trials can occur at any stage of testing.

A number of companies have suffered significant setbacks in the advancement of clinical trials, even after earlier clinical trials have shown promising results and we cannot be certain that we will not face similar setbacks. Any of our planned clinical trials for our product candidates may not be successful for a variety of reasons,

including the clinical trial designs, the failure to enroll a sufficient number of patients, undesirable side effects and other safety concerns and the inability to demonstrate sufficient efficacy. If a product candidate fails to demonstrate sufficient safety or efficacy, we would experience potentially significant delays in, or be required to abandon, development of such product candidate. Significant clinical trial delays could also allow our competitors to bring products to market before we do or shorten any periods during which we have the exclusive right to commercialize our product candidates and impair our ability to commercialize our product candidates and may harm our business and results of operations.

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

We have, and from time to time, we may publicly disclose interim, top-line or preliminary data from the clinical trials we conduct, which are based on a preliminary analysis of then-available data. The final results from these clinical trials and any related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular 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. In addition, 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 becomes available. As a result, the top-line or preliminary results that we report may differ from future results of the same trial, or different conclusions or considerations may qualify such results, once additional data has been received and fully evaluated. Top-line or preliminary data also remains subject to audit and verification procedures that may result in the final data being materially different from the top-line or preliminary data we previously published. As a result, top-line and preliminary data should be viewed with caution until final data is available and published. 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 clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. If the interim, top-line or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, the product candidates we develop may be harmed, which could harm our business, financial condition, results of operations and prospects.

Our attempts to develop MN-001 (tipelukast) in Nonalcoholic Steatohepatitis (NASH) and Nonalcoholic Fatty Liver Disease (NAFLD) may detract from our efforts to develop other product candidates and may limit the effectiveness of our product development efforts as a whole.

We have decided to pursue development of MN-001 (tipelukast) in NASH and NAFLD. These activities may divert financial and management resources from our other product development activities and may limit our ability to complete or continue those other programs.

In order to commercialize a therapeutic drug successfully, a product candidate must receive regulatory approval after the successful completion of clinical trials, which can be lengthy, complex and costly, have a high risk of failure and can be delayed or terminated at any time.

Our product candidates are subject to extensive government regulations related to development, clinical trials, manufacturing and commercialization. The process of obtaining FDA and other regulatory approvals is lengthy, costly, time-consuming, uncertain and subject to unanticipated delays. To receive regulatory approval for the commercial sale of any of our product candidates, we must conduct, at our own expense, adequate and well-controlled clinical trials in human patients to demonstrate the efficacy and safety of the product candidate. Clinical testing is complex, expensive, takes many years and has an uncertain outcome. To date, we have obtained regulatory

authorization to conduct clinical trials for our product development programs. Investigational New Drug Applications were approved by the FDA and are active for our product candidates.

It may take years to complete the clinical development necessary to commercialize our product candidates, and delays or failure can occur at any stage, which may result in our inability to market and sell any of our product candidates that are ultimately approved by the FDA or foreign regulatory authorities. Our clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical and/or non-clinical testing. Interim results of clinical trials do not necessarily predict final results, and success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials even after obtaining promising results in earlier clinical trials. In addition, any delays in completing clinical trials or the rejection of data from a clinical trial by a regulatory authority will result in increased development costs and could have a material adverse effect on the development of the impacted product candidate.

In connection with the conduct of clinical trials for each of our product candidates, we face many risks, including the risks that:

- the product candidate may not prove to be effective in treating the targeted indication;
- clinical trial participants and/or patients may experience serious adverse events or other undesirable drug-related side effects;
- the results may not confirm the positive results of earlier trials;
- the FDA or other regulatory authorities may not agree with our proposed development plans or accept the results of completed clinical trials; and
- our planned clinical trials and the data collected from such clinical trials may be deemed by the FDA or other regulatory authorities not to be sufficient, which would require additional development for the product candidate before it can be evaluated in late stage clinical trials or before the FDA will consider an application for marketing approval.

If we do not complete clinical development of our product candidates successfully, we will be unable to obtain regulatory approval to market products and generate revenues from such product candidates. We may also fail to obtain the necessary regulatory approvals if we have inadequate financial or other resources to advance our product candidates through the clinical trial process. In addition, even if we believe that the preclinical and clinical data are sufficient to support regulatory approval for a product candidate, the FDA and foreign regulatory authorities may not ultimately approve such product candidate for commercial sale in any jurisdiction, which would limit our ability to generate revenues and adversely affect our business. In addition, even if our product candidates receive regulatory approval, they remain subject to ongoing FDA regulations, including obligations to conduct additional clinical trials, changes to the product label, new or revised regulatory requirements for manufacturing practices, written advisements to physicians, and/or a product recall or withdrawal.

We are subject to stringent regulation of our product candidates, which could delay the development and commercialization of our product candidates.

We, our third party manufacturers, service providers, suppliers and partners, if any, and our product candidates are subject to stringent regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. None of our product candidates can be marketed in the United States until it has been approved by the FDA. None of our product candidates has been approved by the FDA to date, and we may never receive FDA approval for any of our product candidates. Obtaining FDA approval for a product takes many years of clinical development and requires substantial resources. Additionally, changes in regulatory requirements and guidance may occur or new information regarding the product candidate or the target indication may emerge, and we may need to perform additional, unanticipated non-clinical or clinical testing of our product candidates or amend clinical trial protocols to reflect these changes. Any additional unanticipated testing would add costs and could delay or result in the denial of regulatory approval for a product candidate. These regulatory requirements may limit the

size of the market for the product candidate or result in the incurrence of additional costs. Any delay or failure in obtaining required approvals could substantially reduce or negate our ability to generate revenues from the particular product candidate.

In addition, both before and after regulatory approval, we, our partners and our product candidates are subject to numerous FDA requirements, including requirements related to testing, manufacturing, quality control, labeling, advertising, promotion, distribution and export. The FDA's requirements may change and additional government regulations may be promulgated that could affect us, our partners and our product candidates. Given the number of recent high profile adverse safety events with certain drug products, the FDA may require, as a condition of approval, costly risk management programs, which may include safety surveillance, restricted distribution and use, patient education, enhanced labeling, special packaging or labeling, expedited reporting of certain adverse events, preapproval of promotional materials and restrictions on direct-to-consumer advertising. Furthermore, we cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad.

In order to market any of our products outside of the United States, we and our strategic partners and licensees must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods beyond the requirements of the FDA and the time required to obtain approval in other countries might differ from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks detailed above regarding FDA approval in the United States. Regulatory approval in one country, including FDA approval in the United States, does not ensure regulatory approval in another. In addition, a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others. A product candidate may not be approved for all indications that we request, which would limit the uses of our product and adversely impact our potential royalties and product sales, and any approval that we receive may be subject to limitations on the indicated uses for which the product may be marketed or require costly, post-marketing follow-up studies.

If we fail to comply with applicable regulatory requirements in the United States or other countries, we may be subject to regulatory and other consequences, including fines and other civil penalties, delays in approving or failure to approve a product, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions, interruption of manufacturing or clinical trials, injunctions and criminal prosecution, any of which would harm our business.

Even if our product candidates receive regulatory approval, they may still face future development and regulatory difficulties.

Even if U.S. regulatory approval is obtained, the FDA may still impose significant restrictions on a product's indicated uses or marketing or impose ongoing requirements for potentially costly post-approval studies, including additional research and development and clinical trials. Any of these restrictions or requirements could adversely affect our potential product revenues. For example, the label ultimately approved for any of our other product candidates or any other product candidates that we may in-license or acquire, if any, may include a restriction on the terms of its use, or it may not include one or more of our intended indications.

Our product candidates, if approved, will also be subject to ongoing FDA requirements for the labeling, packaging, storage, advertising, promotion, record-keeping and submission of safety and other post-market information on the drug. In addition, approved products, manufacturers and manufacturers' facilities are subject to continual review and periodic inspections. If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If our product candidates fail to comply with applicable regulatory requirements, such as commercial good manufacturing practices (cGMPs), a regulatory agency may:

- issue warning letters or untitled letters;

- require us to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for non-compliance;
- impose other civil or criminal penalties;
- suspend regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications filed by us;
- impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products or require a product recall.

The FDA policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business.

Moreover, the ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business.

The ability of the FDA and other government agencies to properly administer their functions is highly dependent on the levels of government funding and the ability to fill key leadership appointments, among various factors. Delays in filling or replacing key positions could significantly impact the ability of the FDA and other agencies to fulfill their functions, and could greatly impact healthcare and the pharmaceutical industry.

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. Further, three decisions from the U.S. Supreme Court in July 2024 may lead to an increase in litigation against regulatory agencies that could create uncertainty and thus negatively impact our business. The first decision overturned established precedent that required courts to defer to regulatory agencies' interpretations of ambiguous statutory language. The second decision overturned regulatory agencies' ability to impose civil penalties in administrative proceedings. The third decision extended the statute of limitations within which entities may challenge agency actions. However, the specific, lasting effects of these decisions, which may vary within different judicial districts and circuits, is unknown. We also cannot predict the extent to which FDA and SEC regulations, policies, and decisions may become subject to increasing legal challenges, delays, and changes. For example, these cases may result in increased litigation by companies against the FDA, and impact the FDA's authority, lead to uncertainties in the industry, and disrupt the FDA's normal operations, which could impact the timely review of any regulatory filings or applications we submit to the FDA.

Further, if a prolonged government shutdown occurs, or if global health concerns 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.

We have received Fast Track and/or Orphan Drug designation for certain of our product candidates and may seek such designation, breakthrough therapy and/or priority review for other product candidates in the future. We may not receive such designations, and even if we do, we may not maintain such designations, and such designations may not lead to faster development, regulatory review or approval, and will not increase the likelihood that the product candidate will receive marketing approval.

We have received Fast Track designation for certain of our product candidates, including MN-001 (tipelukast) for the potential treatment of NASH with fibrosis and MN-166 (ibudilast) for the potential treatment of progressive MS, the potential treatment of Amyotrophic Lateral Sclerosis (ALS) and we hope to benefit from the FDA's Fast Track and priority review programs.

Product candidates with Fast Track designation may benefit from early and frequent communications with the FDA, potential priority review and the ability to submit a rolling application for regulatory review. Fast Track designation applies to both the product candidate and the specific indication for which it is being studied. If any of our product candidates receive Fast Track designation but do not continue to meet the criteria for Fast Track designation, or if our clinical trials are delayed, suspended or terminated, or put on clinical hold due to unexpected adverse events or issues with clinical supply, we will not receive the benefits associated with the Fast Track program. Furthermore, Fast Track designation does not change the standards for approval. The receipt of Fast Track designation for a product candidate may not result in a faster development or regulatory review or approval process compared to products considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if any product candidate qualifies for Fast Track designation, the FDA may later decide that the product candidates no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. Fast Track designation alone does not guarantee qualification for the FDA's priority review procedures.

We have also received Orphan Drug designation for several of our product candidates, including for MN-166 (ibudilast) for the potential treatment of ALS. We may not be able to obtain or maintain Orphan Drug exclusivity in the United States for those product candidates. We may not be the first to obtain marketing approval of any product candidate for which we have obtained Orphan Drug designation for the orphan-designated indication due to the uncertainties associated with developing pharmaceutical products. In addition, exclusive marketing rights in the United States may be limited if we seek FDA marketing approval for an indication broader than the orphan designated indication. Additionally, any product candidate with Orphan Drug designation may lose such designation if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Additionally, after an orphan drug is approved, the FDA could subsequently approve another application for the same drug for the same indication if the FDA concludes that the later drug is shown to be safer, more effective or makes a major contribution to patient care. Orphan Drug exclusive marketing rights in the United States also may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. In addition, others may obtain Orphan Drug exclusivity for products addressing the same diseases or conditions as products we are developing, thus limiting our ability to compete in the markets addressing such diseases or conditions for a significant period of time. Orphan Drug designation neither shortens the development time or regulatory review time of a drug nor gives the product candidate any advantage in the regulatory review or approval process or entitles the product candidate to priority review.

Under the Orphan Drug Act, the FDA may grant Orphan Drug designation to a drug intended to treat a rare disease or condition or for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for a disease or condition will be recovered from sales in the United States for that drug. If a product that has Orphan Drug designation subsequently receives the first FDA approval for the indication for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, including a full NDA, to market the same drug or biologic for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity.

We may seek priority review with the FDA (review within a six-month time frame from the time a complete NDA is accepted for filing compared to 10 months under standard review) for one or more of our current or future product candidates. Under FDA policies, a product candidate is eligible for priority review if the product candidate provides a significant improvement compared to marketed drugs in the treatment, diagnosis or prevention of a disease. The FDA determines whether a drug qualifies for priority review after an NDA for such drug is submitted to the FDA. Therefore, until NDAs are submitted for our product candidates, we cannot be assured that they will be granted priority review. Additionally, even if priority review is granted for one of our product candidates, the FDA does not always meet its six-month Prescription Drug User Fee Act (PDUFA) goal date for priority review and the review process is often extended by FDA requests for additional information or clarification.

We may seek Breakthrough Therapy designation for one or more of our current or future product candidates. Designation as a Breakthrough Therapy is largely within the discretion of the FDA. Accordingly, even if we believe that a product candidate meets the criteria for designation as a Breakthrough Therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a Breakthrough Therapy designation for a product candidate may not result in a faster development process, review or approval compared to candidate products considered for approval under non-expedited FDA review procedures and does not assure ultimate approval by the FDA. In addition, even if one or more product candidates qualify as breakthrough therapies, the FDA may later decide that the product candidate no longer meets the conditions for qualification and revoke the designation.

The FDA has broad discretion whether or not to grant Breakthrough Therapy, Fast Track and/or Orphan Drug designation to any product candidate. Accordingly, even if we believe that a product candidate meets the criteria for designation as a Breakthrough Therapy or Orphan Drug designation, the FDA may disagree and instead determine not to make such designation. Even if we receive breakthrough therapy and/or Orphan Drug designation, the receipt of such designation may not result in a faster development or regulatory review or approval process compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if a product candidate qualifies as a breakthrough therapy or Orphan Drug, the FDA may later decide that it no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. The failure to obtain a Breakthrough Therapy, Fast Track and/or Orphan Drug designation or admission for any product candidates we may develop or the inability to maintain that designation for the duration of the applicable period could reduce our ability to make sufficient sales of the applicable product candidate to balance our expenses incurred to develop it, which would have a negative impact on our operational results and financial condition. The FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program. Fast track designation alone does not guarantee qualification for the FDA's priority review procedures. Fast Track or Breakthrough Therapy designation for our product candidates may not actually lead to a faster review process, and a delay in the review process or in the approval of our product candidates will delay revenue from their potential sales and will increase the capital necessary to fund these product candidate development programs.

Any product candidates that we advance into clinical trials may cause undesirable side effects or have other properties that could delay or prevent regulatory approval or commercialization or limit its commercial potential.

Undesirable side effects caused by any of our product candidates that we advance into clinical trials could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in the denial of regulatory approval by the FDA or other regulatory authorities for any or all targeted indications, or cause us to evaluate the future of our development programs. This, in turn, could prevent us from commercializing the affected product candidate and generating revenues from its sale.

In addition, if any product candidates we may develop receives marketing approval and we or others later identify undesirable side effects caused by the product, a number of significant negative consequences could result, including:

- regulatory authorities may withdraw their approval of the product or place restrictions on the way it is prescribed;

- regulatory authorities may require a larger clinical benefit for approval to offset the risk;

- regulatory authorities may require the addition of labeling statements that could diminish the usage of the product or otherwise limit the commercial success of the product;

- we may be required to change the way the product is administered, conduct additional clinical trials or change the labeling of the product or implement a risk evaluation and mitigation strategy;

- we may choose to discontinue sale of the product;

- we could be sued and held liable for harm caused to patients;

- we may not be able to enter into collaboration agreements on acceptable terms and execute our business model; and

- our reputation may suffer.

Delays in the commencement or completion of clinical trials, or suspension or termination of our clinical trials, could result in increased costs to us and delay or limit our ability to obtain regulatory approval for our product candidates.

If we experience delays in the commencement or completion of our clinical trials, we could incur significantly higher product development costs and our ability to obtain regulatory approvals for our product candidates could be delayed or limited. The commencement and completion of clinical trials requires us to identify and maintain a sufficient number of study sites and enroll a sufficient number of patients at such sites. We do not know whether enrollment in our future clinical trials for our product candidates will be completed on time, or whether our additional planned and ongoing clinical trials for our product candidates will be completed on schedule, if at all.

The commencement and completion of clinical trials can be delayed for a variety of other reasons, including delays in:

- regulatory approval to commence or amend a clinical trial;

- reaching agreements on acceptable terms with prospective clinical research organizations or Contract Research Organizations (CROs), and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;

- recruiting and enrolling patients to participate in clinical trials;

- retaining patients who have initiated a clinical trial but who may be prone to withdraw due to the treatment protocol, lack of efficacy, personal issues or side effects from the therapy or who are lost to further follow-up;

- manufacturing sufficient quantities of a product candidate; and

- Institutional Review Board (IRB) approval or approval from foreign counterparts to conduct or amend a clinical trial at a prospective site.

In addition, a clinical trial may be delayed, suspended or terminated by us, the FDA or other regulatory authorities due to a number of factors, including:

- ongoing discussions with regulatory authorities regarding the scope or design of our clinical trials or requests by them for supplemental information with respect to our clinical trial results, which may result in the imposition of a clinical hold on the IND for any clinical trial, as well as the inability to resolve any outstanding concerns with the FDA so that a clinical hold already placed on the IND may be lifted and the clinical trial may begin;

- inspections of our own clinical trial operations, the operations of our CROs or our clinical trial sites by the FDA or other regulatory authorities, which may result in the imposition of a clinical hold or potentially prevent us from using some of the data generated from our clinical trials to support requests for regulatory approval of our product candidates;

- our failure or inability, or the failure or inability of our CROs, clinical trial site staff or other third party service providers involved in the clinical trial, to conduct clinical trials in accordance with regulatory requirements or our clinical protocols;

- lower than anticipated enrollment or retention rates of patients in clinical trials;

- new information suggesting unacceptable risk to subjects or unforeseen safety issues or any determination that a clinical trial presents unacceptable health risks;

- insufficient supply or deficient quality of product candidates or other materials necessary for the conduct of our clinical trials;

- lack of adequate funding to continue the clinical trial, including the incurrence of unforeseen costs due to enrollment delays, requirements to conduct additional trials and studies and increased expenses associated with the services of our CROs and other third parties; and

- the formulation or dosing regimen of a product candidate may result, unintentionally, in patient non-compliance, leading to low patient retention rates, incomplete data to conduct an adequate analysis, and failure to complete the trial.

If we experience delays in the completion of our clinical trials for a product candidate, the commercial prospects for such product candidate may be harmed, we may incur increased costs for development of such product candidate and our ability to obtain regulatory approval for such product candidate could be delayed or limited. Many of the factors that cause or lead to delays in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval for a product candidate. In addition, any amendment to a clinical trial protocol may require us to resubmit our clinical trial protocols to IRBs or their foreign counterparts for reexamination, which may delay or otherwise impact the costs, timing or successful completion of a clinical trial.

The loss of any rights to develop and market any of our product candidates could significantly harm our business.

We license the rights to certain compounds to develop and market our product candidates.

We are obligated to develop and commercialize certain product candidates in accordance with mutually agreed upon terms and conditions. Our ability to satisfy some or all of the terms and conditions of our license agreements is dependent on numerous factors, including some factors that are outside of our control. Any of our license agreements may be terminated if we breach our obligations under the agreement materially and fail to cure any such breach within a specified period of time.

If any of our license agreements is terminated, we would have no further rights to develop and commercialize the product candidate that is the subject of the license. The termination of any of our license agreements could materially and adversely affect our business.

Our business could be adversely affected by the effects of health pandemics or epidemics in regions where we or third parties on which we rely have significant manufacturing facilities, concentrations of clinical trial sites or other business operations, which could materially affect our operations globally, including at our headquarters in San Diego and at our clinical trial sites, as well as the business or operations of our manufacturers, CROs or other third parties with whom we conduct business.

Our business, operations and clinical development timelines could be adversely affected by health pandemics, epidemics or any other health crisis in regions where we have clinical trial sites or other business

operations, and could cause significant disruption in the operations of CROs upon whom we rely. Site initiation and patient enrollment could be delayed or suspended due to prioritization of hospital resources toward the health epidemics or patients not having a desire to enroll in clinical trials due to concerns. For example, during the COVID-19 pandemic, we saw a decrease in the number of patient visits at some clinical trial sites, which we believe resulted in slower enrollment in our clinical trials than would have occurred without the COVID-19 pandemic. In addition, some patients may not be able to comply with clinical trial protocols and the ability to conduct follow-up visits with treated patients may be limited if patients do not want to participate in follow up visits due to concerns regarding health epidemics or if quarantines impede patient movement or interrupt healthcare services. There may be shortages in the raw materials used in the manufacturing of our product candidates or laboratory supplies for our preclinical studies and clinical trials, in each case, because of ongoing efforts to address the outbreak. We could be negatively impacted by any other illness or communicable disease, or any other public health crisis that, like the COVID-19 pandemic, results in economic and trade disruptions, including the disruption of global supply chains.

The response to a health epidemic may redirect resources with respect to regulatory matters in a way that would adversely impact our ability to pursue marketing approvals. In addition, we may face impediments to regulatory meetings and potential approvals due to measures intended to limit in-person interactions. Furthermore, third parties, including manufacturers, medical institutions, clinical investigators, CROs and consultants with whom we conduct business, are similarly adjusting their operations and assessing their capacity in light of a health epidemic. If these third parties continue to experience shutdowns or business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively impacted.

The extent to which a health pandemic or epidemic impacts our business, clinical trials, results of operations and financial condition will depend on future developments, which are highly uncertain and cannot be predicted, including, but not limited to, the duration of the pandemic or epidemic, its severity, the actions to contain the virus or address its impact, and how quickly and to what extent government orders and mandates are lifted and normal economic and operating activities can resume. Further, while the potential economic impact of any health pandemic or epidemic may be difficult to assess or predict, it could result in significant disruptions of global financial markets, which could reduce our ability to access capital, which could in the future negatively affect our liquidity. To the extent a health pandemic or epidemic adversely affects our business, clinical trials, results of operations and financial condition, it may also have the effect of heightening many of the other risks described in this “Risk Factors” section. The ultimate impact of a health epidemic is highly uncertain and subject to change.

If our competitors develop and market products more rapidly than we do or that are more effective, safer or more affordable than our product candidates, our commercial opportunities may be negatively impacted.

The biotechnology and pharmaceutical industries are highly competitive and subject to rapid and intense technological change. We face, and will continue to face, competition from pharmaceutical and biotechnology companies, as well as numerous academic and research institutions and governmental agencies, in the United States and abroad. Some of these competitors have products or are pursuing the development of drugs that target the same diseases and conditions that are the focus of our product development programs. We cannot assure you that developments by others will not render our product candidates obsolete or noncompetitive. Many of our competitors have products that have been approved or are in advanced development and may succeed in developing drugs that are more effective, safer, more affordable or more easily administered than ours, or that achieve patent protection or commercialization sooner than our products. Our competitors may also develop alternative therapies that could further limit the market for any product candidates that we are able to obtain approval for, if at all. In addition, new developments, including the development of other drug technologies and methods of preventing the incidence of disease, occur in the pharmaceutical industry at a rapid pace. These developments may render our product candidates obsolete or noncompetitive.

In many of our target disease areas, potential competitors are working to develop new compounds with different mechanisms of action and attractive efficacy and safety profiles. Many of our competitors have substantially greater financial, research and development resources, including personnel and technology, clinical trial experience, manufacturing, sales and marketing capabilities and production facilities than we do. Smaller companies also may prove to be significant competitors, particularly through proprietary research discoveries and collaboration arrangements with large pharmaceutical and established biotechnology companies.

Our competitors may obtain regulatory approval of their products more rapidly than we are able to or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidates. Our competitors may also develop drugs that are more effective and less costly than ours and may also be more successful than us in manufacturing and marketing their products. We also expect to face similar competition in our efforts to identify appropriate collaborators or partners to help develop or commercialize our product candidates.

We will depend on strategic collaborations with third party partners to develop and commercialize selected product candidates and will not have control over a number of key elements relating to the development and commercialization of these product candidates if we are able to achieve such third party arrangements.

A key aspect of our strategy is to seek strategic collaborations with partners, such as large pharmaceutical companies, that are willing to conduct later-stage clinical trials and further develop and commercialize selected product candidates. To date, we have not entered into any such collaborative arrangements, and we may not be able to enter into any collaborations or otherwise monetize these product candidates on acceptable terms, if at all.

By entering into a strategic collaboration with a partner, we may rely on the partner for financial resources and for development, regulatory and commercialization expertise. Even if we are successful in entering into a strategic collaboration for one of our product candidates, we will not have control over a number of key elements relating to the development and commercialization of these product candidates. Further, our partner may fail to develop or effectively commercialize the product candidate because such partner:

- does not have sufficient resources or decides not to devote the necessary resources due to internal constraints such as limited cash or human resources;
- decides to pursue a competitive potential product developed outside of the collaboration;
- cannot obtain the necessary regulatory approvals;
- determines that the market opportunity is not attractive; or
- cannot manufacture the necessary materials in sufficient quantities from multiple sources or at a reasonable cost.

We also face competition in our search for partners from other biotechnology and pharmaceutical companies worldwide, many of whom are larger and able to offer more attractive deals in terms of financial commitments, contribution of human resources, or development, manufacturing, regulatory or commercial expertise and support.

If we are not successful in attracting partners and entering into collaborations on acceptable terms for these product candidates or otherwise monetizing these product candidates, we may not be able to complete development of or obtain regulatory approval for such product candidates. In such event, our ability to generate revenues from such products and achieve or sustain profitability would be significantly hindered.

We rely on third parties to conduct our clinical trials, and we may incur additional development costs, experience delays in the commencement and completion of clinical trials, and be unable to obtain regulatory approval for or commercialize our product candidates on our anticipated timeline if these third parties do not successfully carry out their contractual duties or meet expected deadlines, which may have an adverse effect on our business and prospects.

We do not have the ability to independently conduct our clinical trials. We currently rely extensively on third parties, such as CROs, medical institutions, clinical investigators, contract laboratories and other service providers to perform important functions related to the conduct of our clinical trials, the collection and analysis of data and the preparation of regulatory submissions. Although we design and/or manage our current clinical trials to ensure that each clinical trial is conducted in accordance with its investigational plan and protocol, we do not have the ability to conduct all aspects of our clinical trials directly for our product candidates. We expect to continue to rely upon third parties to conduct additional clinical trials of potential future product candidates. These third parties are not our

employees, and except for remedies available to us under our agreements with such third party, we have limited ability to control the amount or timing of resources that any such third party will devote to our clinical trials. Some of these third parties may terminate their engagements with us at any time. If we need to enter into alternative arrangements with a third party, it would delay our development activities.

The FDA requires us and our third parties to comply with regulations and standards, commonly referred to as good clinical practices (GCPs) for conducting, monitoring, recording and reporting the results of clinical trials to ensure that the data and results are scientifically credible and accurate and that the trial subjects are adequately informed of the potential risks of participating in clinical trials. Our reliance on these third parties does not relieve us of these responsibilities and requirements. The CROs, medical institutions, clinical investigators, contract laboratories and other service providers that we employ in the conduct of our clinical trials are not our employees, and we cannot control the amount or timing of resources that they devote to our product development programs. If any of these third parties fails to devote sufficient care, time and resources to our product development programs, if its performance is substandard, or if any third party is inspected by the FDA and found not to be in compliance with GCPs, it will delay the completion of the clinical trial in which they are involved and the progress of the affected development program. The CROs and other third party service providers with which we contract for execution of our clinical trials play a significant role in the conduct of the clinical trials and the subsequent collection and analysis of data. Any failure of the CROs and other third party service providers to meet their obligations could adversely affect clinical development of our product candidates. Moreover, these third parties may have relationships with other commercial entities, some of which may have competitive products under development or currently marketed, and our competitive position could be harmed if they assist our competitors. In addition, the operations of our CROs and other third party service providers may be constrained or disrupted by widespread health pandemics or epidemics. If any of these third parties does not successfully carry out their contractual duties or obligations or meet expected deadlines, or if the quality or accuracy of the clinical data is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for our product candidates. In addition, while we believe that there are numerous alternative sources to provide these services, we might not be able to enter into replacement arrangements without delays or additional expenditures if we were to seek such alternative sources. Switching or adding additional CROs, investigators and other third parties involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays can occur, which could materially impact our ability to meet our desired clinical development timelines. Government measures taken in response to global health pandemics or epidemics have also had a significant impact on many CROs. Although we plan to carefully manage our relationships with our CROs, investigators and other third parties, we may nonetheless encounter challenges or delays in the future, which could have a material and adverse impact on our business, financial condition and prospects.

We rely, and intend to rely, on third party manufacturers to produce our product candidates, which may result in delays in our clinical trials and the commercialization of products, as well as increased costs.

We have no manufacturing facilities, and we do not intend to develop facilities for the manufacture of our product candidates for clinical trials or commercial purposes in the foreseeable future. We rely, and expect to continue to rely, on third party manufacturers to produce, in collaboration with us, sufficient quantities of our product candidates for clinical trials, and we plan to contract with third party manufacturers to produce sufficient quantities of any product candidates that may be approved by the FDA or other regulatory authorities for commercial sale. While we believe that there are competitive sources available to manufacture our product candidates, we may not be able to enter into arrangements without delays or additional expenditures. We cannot estimate these delays or costs with certainty.

Reliance on third party manufacturers limits our ability to control certain aspects of the manufacturing process and therefore exposes us to a variety of significant risks, including risks related to our ability to commercialize any products approved by regulatory authorities or conduct clinical trials, reliance on such third parties for regulatory compliance and quality assurance, and the refusal or inability of a third party manufacturer to supply our requirements on a long-term basis. In addition, manufacturers of pharmaceutical products often encounter difficulties in production, particularly in scaling up initial production. These problems include difficulties with production costs and yields, quality control, including stability of the product candidate and quality assurance testing, shortages of qualified personnel and compliance with federal, state and foreign regulations. In addition, the global health pandemics or epidemics may impact our third party manufacturers from producing sufficient quantities

of any product candidate. Also, our manufacturers may not perform as agreed. If our manufacturers were to encounter any of these difficulties, our ability to timely produce our product candidates for clinical trials and commercial sale may be interrupted, which could result in delayed clinical trials or delayed regulatory approval and lost or delayed revenues.

We may not be able to establish or maintain any commercial manufacturing and supply arrangements on commercially reasonable terms that we require for purposes of commercializing a product. Any failure by us to secure or maintain any such required commercial supply agreements could result in interruption of supply and lost or delayed revenues, which would adversely affect our business. Any problems or delays we experience in preparing for commercial-scale manufacturing of a product candidate may result in a delay in FDA or other regulatory approval of the product candidate or may impair our ability to manufacture commercial quantities, which would adversely affect our business. For example, our manufacturers will need to produce specific batches of a product candidate to demonstrate acceptable stability under various conditions and for commercially viable lengths of time. We and our third party manufacturers will need to demonstrate to the FDA and other regulatory authorities this acceptable stability data for the product candidate, as well as validate methods and manufacturing processes, in order to receive regulatory approval to commercialize such product candidate.

Our manufacturers are obligated to operate in accordance with FDA-mandated cGMPs and, in some cases, International Convention on Harmonization (ICH), standards. A failure of any of our third party manufacturers to establish and follow cGMPs and/or ICH standards and to document their adherence to such practices may lead to significant delays in our ability to timely conduct and complete clinical trials, obtain regulatory approval of product candidates or launch of our products into the market. In addition, changing third party manufacturers is difficult. For example, a change in third party manufacturer for a particular product candidate requires re-validation of the manufacturing processes and procedures in accordance with cGMPs, which may be costly and time-consuming and, in some cases, our manufacturers may not provide us with adequate assistance to transfer the manufacturing processes and procedures for our product candidates to new manufacturers or may possess intellectual property rights covering parts of these processes or procedures for which we may need to obtain a license. Failure by our third party manufacturers or us to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of regulatory approvals, seizures or recalls of products, operating restrictions and criminal prosecutions.

We, or our third party manufacturers, may not be able to manufacture our product candidates in sufficient quality or commercial quantities, which would delay or prevent us from commercializing our product candidates.

To date, our product candidates have been manufactured in small quantities for preclinical studies and clinical trials. If any of our product candidates is approved by the FDA or comparable regulatory authorities in other countries for commercial sale, we or our third party manufacturers will need to manufacture such product candidate in larger quantities. We or our third party manufacturers may not be able to increase successfully the manufacturing capacity for any of our product candidates in a timely or economic manner, or at all. Significant scale-up of manufacturing may require additional validation studies, which the FDA must review and approve. If we or our third party manufacturers are unable to increase successfully the manufacturing capacity for a product candidate, the regulatory approval or commercial launch of that product candidate may be delayed or there may be a shortage in supply. Our product candidates require precise, high-quality manufacturing. Our failure to achieve and maintain these high manufacturing standards in collaboration with our third party manufacturers, including the incidence of manufacturing errors, could result in patient injury or death, product recalls or withdrawals, delays or failures in product testing or delivery, cost overruns or other problems that could harm our business, financial condition and results of operations.

Materials necessary to manufacture our product candidates may not be available on commercially reasonable terms, or at all, which may delay the development and commercialization of our product candidates.

We rely on the third party manufacturers of our product candidates to purchase from third party suppliers the materials necessary to produce the active pharmaceutical ingredients (API) and product candidates for our clinical trials, and we will rely on such manufacturers to purchase such materials to produce the API and finished product for any commercial distribution of our products if we obtain marketing approval. Suppliers may not sell these materials to our manufacturers at the time they need them in order to meet our required delivery schedule or on commercially reasonable terms, if at all. We do not have any control over the process or timing of the acquisition of

these materials by our manufacturers. Moreover, we currently do not have any agreements for the production of these materials. If our manufacturers are unable to obtain these materials for our clinical trials, testing of the affected product candidate would be delayed, which may significantly impact our ability to develop the product candidate. If we or our manufacturers are unable to purchase these materials after regulatory approval has been obtained for one of our products, the commercial launch of such product would be delayed or there would be a shortage in supply of such product, which would harm our ability to generate revenues from such product and achieve or sustain profitability.

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

As product candidates progress through preclinical to late-stage clinical trials to marketing approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize yield, manufacturing batch size, minimize costs and achieve consistent quality 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 altered materials. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commercialize our product candidates and generate revenue.

Our product candidates, if approved for sale, may not gain acceptance among physicians, patients and the medical community, thereby limiting our potential to generate revenues.

If any of our product candidates is approved for commercial sale by the FDA or other regulatory authorities, the degree of market acceptance of any approved product by physicians, healthcare professionals and third party payers and our profitability and growth will depend on a number of factors, including:

- demonstration of efficacy and safety;
- changes in the standard of care for the targeted indication;
- relative convenience and ease of administration;
- the prevalence and severity of any adverse side effects;
- availability, cost and potential advantages of alternative treatments, including less expensive generic drugs;
- pricing and cost effectiveness, which may be subject to regulatory control;
- effectiveness of our or any of our partners' sales and marketing strategies;
- publicity concerning our products or competing products;
- the product labeling or product insert required by the FDA or regulatory authority in other countries; and
- the availability of adequate third party insurance coverage or reimbursement.

If any product candidate that we develop does not provide a treatment regimen that is as beneficial as, or is perceived as being as beneficial as, the current standard of care or otherwise does not provide patient benefit, that product candidate, if approved for commercial sale by the FDA or other regulatory authorities, likely will not achieve market acceptance. Our ability to effectively promote and sell any approved products will also depend on pricing and cost-effectiveness, including our ability to produce a product at a competitive price and our ability to obtain sufficient third party coverage or reimbursement. If any product candidate is approved but does not achieve an adequate level of acceptance by physicians, patients and third party payers, our ability to generate revenues from that product would be substantially reduced. In addition, our efforts to educate the medical community and third

party payers on the benefits of our product candidates may require significant resources and may never be successful.

If our products are not accepted by the market or if users of our products are unable to obtain adequate coverage of and reimbursement for our products from government and other third party payers, our revenues and profitability will suffer.

Our ability to commercialize our product candidates, if approved, successfully will depend in significant part on pricing and cost effectiveness, including our ability to produce a product at a competitive price and our ability to obtain appropriate coverage of and reimbursement for our products and related treatments from governmental authorities, private health insurers and other organizations, such as health maintenance organizations (HMOs). Third party payers are increasingly challenging the prices charged for medical products and services. We cannot provide any assurances that third party payers will consider our products cost-effective or provide coverage of and reimbursement for our products, in whole or in part.

Uncertainty exists as to the coverage and reimbursement status of newly approved medical products and services and newly approved indications for existing products. Third party payers may conclude that our products are less safe, less clinically effective or less cost-effective than existing products, and third party payers may not approve our products for coverage and reimbursement. If we are unable to obtain adequate coverage of and reimbursement for our products from third party payers, physicians may limit how much or under what circumstances they will prescribe or administer them. Such reduction or limitation in the use of our products could cause our sales to suffer. Even if third party payers make reimbursement available, payment levels may not be sufficient to make the sale of our products profitable.

Market acceptance and sales of our current or future product candidates will depend in large part on global reimbursement policies and may be affected by future health care reform measures, both in the United States and other key international markets. For example, continuing health care reform in the United States will control or significantly influence the purchase of medical services and products, and may result in inadequate coverage of and reimbursement for our products. Many third party payers are pursuing various ways to reduce pharmaceutical costs, including the use of formularies. The market for our products depends on access to such formularies, which are lists of medications for which third party payers provide reimbursement. These formularies are increasingly restricted, and pharmaceutical companies face significant competition in their efforts to place their products on formularies. This increased competition has led to a downward pricing pressure in the industry. The cost containment measures that third party payers, including government payers, are instituting could have a material adverse effect on our ability to operate profitably.

We are dependent on our management team, particularly our President and Chief Executive Officer, and our experienced scientific staff, and if we are unable to retain, motivate and attract key personnel, our product development programs may be delayed and we may be unable to develop successfully or commercialize our product candidates.

We are dependent upon the continued services of our executive officers and other key personnel, particularly Yuichi Iwaki, M.D., Ph.D., our founder and our President, Chief Executive Officer and Chairman of our board of directors, who has been instrumental in our ability to in-license product candidates from Japanese pharmaceutical companies and secure financing from Japanese institutions. The relationships that certain of our key managers have cultivated with pharmaceutical companies from whom we license product candidates and to whom we expect to out-license product candidates make us particularly dependent upon their continued services with us, whether through employment, service on our board of directors or a consulting agreement. We are also substantially dependent on the continued services of clinical development personnel because of the highly technical nature of our product development programs. We are not presently aware of any plans of our executive officers or key personnel to retire or leave employment. Following termination of employment, these individuals may engage in other businesses that may compete with us.

If we acquire or license new product candidates, our success may depend on our ability to attract, retain and motivate highly qualified management and scientific personnel to manage the development of these new product candidates. In particular, our product development programs depend on our ability to attract and retain highly experienced clinical development personnel. However, we face competition for experienced professional personnel

from numerous companies and academic and other research institutions. Competition for qualified personnel is particularly intense in the San Diego, California area, where our corporate headquarters is located. In addition, we have scientific and clinical advisors who assist us in our product development and clinical strategies. These third parties are not our employees and may have commitments to, or contracts with, other entities that may limit their availability to us, or may have arrangements with other companies to assist in the development of products that may compete with our product candidates.

Although we have employment agreements with key members of management, each of our employees, subject to applicable notice requirements, may terminate his or her employment at any time. We do not carry "key person" insurance covering members of senior management. If we lose any of our key management personnel, we may not be able to find suitable replacements, which would adversely affect our business.

If we are unable to establish sales, marketing and distribution capabilities, whether independently or with third parties, we will be unable to commercialize our product candidates successfully.

To date, we have not sold, marketed or distributed any pharmaceutical products. If we are successful in obtaining regulatory approvals for any of our product candidates or acquiring other approved products, we will need to establish sales, marketing and distribution capabilities on our own or with partners in order to commercialize an approved product. The acquisition or development of an effective sales and marketing infrastructure will require a significant amount of our financial resources and time and could negatively impact our commercialization efforts, including delay of a product launch. We may be unable to establish and manage a sufficient or effective sales force in a timely or cost-effective manner, if at all, and any sales force we do establish may not be capable of generating demand for our products, therefore hindering our ability to generate revenues and achieve or sustain profitability. In addition, if we are unable to develop internal sales capabilities, we will need to contract with third parties or establish a partnership to market and sell the product. If we are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to generate any product revenues, may generate increased expenses and may never become profitable. In addition, although we intend to establish strategic collaborations to market any products approved for sale by regulatory authorities outside of the United States, we may be required to market our product candidates outside of the United States directly if we are unable to establish such collaborations. In that event, we may need to build a corresponding international sales and marketing capability with technical expertise and with supporting distribution capabilities.

Health care reform measures could adversely affect our business.

The business and financial condition of pharmaceutical and biotechnology companies are affected by the efforts of governmental and third party payers to contain or reduce the costs of health care. In the United States and in foreign jurisdictions, there have been, and we expect that there will continue to be, a number of legislative and regulatory proposals aimed at changing the health care system. For example, in some countries, pricing of prescription drugs is subject to government control, and we expect to continue to see proposals to implement similar controls in the United States to continue. Another example of proposed reform that could affect our business is drug reimportation into the United States. Moreover, the pendency or approval of such proposals could result in a decrease in our stock price or our ability to raise capital or to obtain strategic partnerships or licenses. More recently, the Patient Protection and Affordable Care Act imposed numerous reforms that may impact the costs, legal requirements and potential success of our operations.

Any clinical trial programs, marketing, or research collaborations in the European Economic Area (EEA) will subject us to the General Data Protection Regulation, including as implemented in the UK (GDPR).

The GDPR applies to companies established in the EEA, as well as to companies that are not established in the EEA and which, inter alia, collect and use personal data in relation to (i) offering goods or services to, or (ii) monitoring the behavior of, individuals located in the EEA. If we conduct clinical trial programs in the EEA (whether the trials are conducted directly by us or through a clinical vendor or collaborator), or enter into research collaborations involving the monitoring of individuals in the EEA, or market our products to individuals in the EEA, we will be subject to the GDPR. The GDPR puts in place stringent operational requirements for processors and controllers of personal data, including, for example, high standards for obtaining consent from individuals to process their personal data (or reliance on another appropriate legal basis), the provision of robust and detailed disclosures to individuals about how personal data is collected and processed (in a concise, intelligible and easily accessible form),

a comprehensive individual data rights regime (including access, erasure, objection, restriction, rectification and portability), maintaining a record of data processing, data export restrictions governing transfers of data from the EEA, short timelines for certain data breach notifications to be given to data protection regulators or supervisory authorities (and in certain cases, affected individuals), and limitations on retention of personal data. The GDPR also puts in place increased requirements pertaining to health data and other special categories of personal data, and includes within scope, pseudonymized (i.e., key-coded) data. Further, the GDPR provides that EEA member states may establish their own laws and regulations limiting the processing of genetic, biometric, or health data, which could limit our ability to collect, use, and share such data and/or could cause our costs to increase. In addition, there are certain obligations if we contract third party processors in connection with the processing of personal data. If our or our collaborators' or service providers' privacy or data security measures fail to comply with the GDPR requirements, we may be subject to litigation, regulatory investigations, enforcement notices requiring us to change the way we use personal data, or fines of up to 20 million Euros or up to 4% of our total worldwide annual revenue of the preceding financial year, whichever is higher, as well as compensation claims by affected individuals, including class-action type litigation, negative publicity, reputational harm and a potential loss of business and goodwill. Additionally, following the United Kingdom's withdrawal from the European Union, we will have to comply with the GDPR and the GDPR as implemented in the United Kingdom, each regime having the ability to fine up to the greater of €20 million/ £17.5 million, respectively, or 4% of global turnover. The relationship between the United Kingdom and the European Union in relation to certain aspects of data protection law remains subject to change, for example around how data can lawfully be transferred between each jurisdiction, which exposes us to further compliance risk.

We are subject to environmental, health and safety laws and regulations, and we may become exposed to liability and substantial expenses in connection with environmental compliance or remediation activities.

Our operations, including our development, testing and manufacturing activities, are subject to numerous environmental, health and safety laws and regulations. These laws and regulations govern, among other things, the controlled use, handling, release, and disposal of and the maintenance of a registry for, hazardous materials and biological materials, such as chemical solvents, human cells, carcinogenic compounds, mutagenic compounds, and compounds that have a toxic effect on reproduction, laboratory procedures and exposure to blood-borne pathogens. If we fail to comply with such laws and regulations, we could be subject to fines or other sanctions.

As with other companies engaged in activities similar to ours, we face a risk of environmental liability inherent in our current and historical activities, including liability relating to releases of or exposure to hazardous or biological materials. Environmental, health and safety laws and regulations are becoming more stringent. We may be required to incur substantial expenses in connection with future environmental compliance or remediation activities, in which case, the production efforts of our third party manufacturers or our development efforts may be interrupted or delayed.

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

United States and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations, which we collectively refer to as Trade Laws, prohibit, among other things, companies and their employees, agents, clinical research organizations, legal counsel, accountants, consultants, contractors, and other partners from authorizing, promising, offering, providing, soliciting, or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Exports of our products are further subject to export controls and sanctions laws and regulations imposed by the United States government and administered by the United States Departments of State, Commerce, and Treasury. United States export control laws may require a license or other authorization to export products to certain destinations and end users. In addition, United States economic sanctions laws include restrictions or prohibitions on engaging in any transactions or dealings, including receiving investment or financing from, or engaging in the sale or supply of products and services to, United States sanctioned countries, governments, persons and entities.

Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We also expect our non-United States activities to increase over time. We expect to rely on third parties for research, preclinical studies, and clinical trials

and/or to obtain necessary permits, licenses, patent registrations, and other marketing approvals. We can be held liable for the corrupt or other illegal activities of our personnel, agents, or partners, even if we do not explicitly authorize or have prior knowledge of such activities. Any changes in Trade Laws could result in a decreased ability to export or sell our solutions to, existing or potential customers with international operations. Future changes in Trade Laws and enforcement could also result in increased compliance requirements and related costs which could materially adversely affect our business, results of operations, financial condition and/or cash flows.

We may be sued for product liability, which could result in substantial liabilities that exceed our available resources and damage our reputation.

The development and commercialization of drug products entails significant product liability risks. Product liability claims may arise from use of any of our product candidates in clinical trials and the commercial sale of any approved products. If we cannot successfully defend ourselves against these claims, we will incur substantial liabilities. Regardless of merit or eventual outcome, product liability claims may result in:

- withdrawal of clinical trial participants;
- termination of clinical trial sites or entire clinical trial programs;
- decreased demand for our product candidates;
- impairment of our business reputation;
- costs of related litigation;
- substantial monetary awards to patients or other claimants;
- loss of revenues; and
- the inability to commercialize our product candidates.

We currently have insurance that covers our clinical trials. We believe our current insurance coverage is reasonably adequate at this time; however, our insurance coverage may not reimburse us or may not be sufficient to reimburse us for all expenses or losses we may suffer. In addition, we will need to increase and expand this coverage as we commence additional clinical trials, as well as larger scale clinical trials, and in the event that any of our product candidates is approved for commercial sale. This insurance may be prohibitively expensive or may not fully cover our potential liabilities. In addition, our inability to obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could prevent or inhibit the regulatory approval or commercialization of products that we or one of our collaborators develop. Successful product liability claims could have a material adverse effect on our business and results of operations. Liability from such claims could exceed our total assets if we do not prevail in any lawsuit brought by a third party alleging that an injury was caused by one of our product candidates.

We expect that our results of operations will fluctuate, which may make it difficult to predict our future performance from period to period.

Our quarterly operating results have fluctuated in the past and are likely to continue to do so in the future. Some of the factors that could cause our operating results to fluctuate from period to period include:

- the status of development of our product candidates and, in particular, the advancement or termination of activities related to our product development programs and the timing of any milestone payments payable under our licensing agreements;
- the execution of other collaboration, licensing and similar arrangements and the timing of payments we may make or receive under these arrangements;

- variations in the level of expenses related to our product development programs;
- the unpredictable effects of collaborations during these periods;
- the timing of our satisfaction of applicable regulatory requirements, if at all;
- the rate of expansion of our clinical development and other internal research and development efforts;
- the costs of any litigation;
- the effect of competing technologies and products and market developments; and
- general and industry-specific economic conditions.

We believe that quarterly or yearly comparisons of our financial results are not necessarily meaningful and should not be relied upon as indications of our future performance.

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

As a public company, we are required to comply with the Sarbanes-Oxley Act of 2002 (Sarbanes-Oxley Act), as well as rules and regulations implemented by the SEC, the Nasdaq Stock Market (Nasdaq) and Japanese securities laws, and incur significant legal, accounting and other expenses as a result. These rules impose various requirements on public companies, including requiring the establishment and maintenance of effective disclosure and financial controls and appropriate corporate governance practices. Our management and other personnel have devoted and will continue to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations increase our legal and financial compliance costs and may make it more difficult and expensive for us to renew our director and officer liability insurance and may result in imposition of reduced policy limits and coverage.

The Sarbanes-Oxley Act requires that we (i) maintain effective internal controls for financial reporting and disclosure controls and procedures and (ii) perform an evaluation of our internal control over financial reporting to allow management to report on the effectiveness of those controls, as required by Section 404 of the Sarbanes-Oxley Act (Section 404). Our listing obligations under the Standard Market of the Tokyo Stock Exchange (TSE) also require that we comply either with Section 404 or equivalent regulations in Japan and we elected to comply with Section 404. Additionally, we are subject to attestation by our independent registered public accounting firm regarding our internal controls over financial reporting as of December 31, 2025 under Japanese securities laws. Our efforts to comply with Section 404 and related regulations have required, and continue to require, the commitment of significant financial and managerial resources. We cannot be certain that a material weakness will not be identified when we test the effectiveness of our controls in the future. If a material weakness is identified, we could be subject to sanctions or investigations by Nasdaq, the SEC, the TSE or other regulatory authorities, which would require additional financial and management resources, costly litigation or a loss of public confidence in our internal controls, which could have an adverse effect on the market price of our stock.

Additionally, there are significant corporate governance and executive compensation related provisions in the Dodd-Frank Wall Street Reform and Consumer Protection Act that require the SEC to adopt additional rules and regulations in these areas. To maintain high standards of corporate governance and public disclosure, we intend to invest all reasonably necessary resources to comply with such compliance programs and rules and all other evolving standards. These investments may result in increased general and administrative costs and a diversion of our management’s time and attention from strategic revenue generating and cost management activities.

We, or our third party CROs or other contractors or consultants, may be subject to information technology systems failures, network disruptions, breaches in data security and computer crime and cyber-attacks, which could result in a material disruption of our product candidates' development programs, compromise sensitive information related to our business or prevent us from accessing critical information, potentially exposing us to liability or otherwise adversely affecting our business.

We are increasingly dependent upon information technology systems, infrastructure and data to operate our business. In the ordinary course of business, we collect, store and transmit confidential information (including but not limited to intellectual property, proprietary business information and personal information). It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We also have outsourced elements of our operations to third parties, and as a result we manage a number of third party contractors who have access to our confidential information.

Information technology system failures, network disruptions, breaches of data security and sophisticated and targeted computer crime and cyber-attacks could disrupt our operations by impeding our drug development programs, including delays in our regulatory efforts, the manufacture or shipment of products, the processing of transactions or reporting of financial results, or by causing an unintentional disclosure of confidential information. Despite our security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or breached due to employee error, malfeasance or other disruptions. Any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. In the ordinary course of our business, we collect and store sensitive data in our data centers and on our networks, including IP, proprietary business information, and personal information of our business partners and employees. Despite our efforts to protect sensitive, confidential or personal data or information, our facilities and systems and those of our third party service providers may be vulnerable to security breaches, theft, misplaced or lost data, programming and/or human errors that could potentially lead to the compromising of sensitive, confidential or personal data or information, improper use of our systems, software solutions or networks, unauthorized access, use, disclosure, modification or destruction of information, defective products, production downtimes and operational disruptions, which in turn could adversely affect our reputation, competitiveness and results of operations. While management has taken steps to address these concerns by conducting employee training, implementing certain data and system redundancy, hardening and fail-over along with other network security, comprehensive monitoring of our networks and systems, maintenance of backup and protective systems and other internal control measures, there can be no assurance that the measures we have implemented to date would be sufficient in the event of a system failure, loss of data or security breach. As a result, in the event of such a failure, loss of data or security breach, our financial condition and operating results could be adversely affected.

Macroeconomic pressures, including those resulting from ongoing geopolitical matters, tariffs, unfavorable market conditions, health epidemics, and regulatory and policy changes, may have an adverse impact on our business, financial results, stock price and results of operations as well as the business of our current and potential customers.

Our results of operations could be adversely affected by unfavorable global and geopolitical economic conditions, such as increased tariffs, decreases in per capital income and level of disposable income, inflation, rising interest rates, and supply chain issues. Ongoing geopolitical matters have also contributed to difficult macroeconomic conditions and exacerbated supply chain issues, resulting in significant economic uncertainty as well as volatility in the financial markets and new regulatory and policy initiatives particularly in the United States. Such conditions may adversely impact our business, financial results, and prospects and our target customers' businesses. In addition, such macroeconomic conditions could impact our ability to access the public markets as and when appropriate or necessary to carry out our operations or our strategic goals. We cannot predict the ongoing extent, duration or severity of these conditions, nor the extent to which we may be impacted.

To the extent macroeconomic conditions worsen, our business, operations and results of operation could be negatively impacted. Additionally, to the extent that there are health pandemics, epidemics or any other health crisis, our operations could be disrupted and our business adversely impacted. Such disruptions or impacts may be similar to those we faced during the COVID-19 pandemic, such as mandated business closures in impacted areas, limitations with employee resources due to stay at home orders or sickness of employees or their families, reduction of our business operations and the business operations of our targeted utility and critical infrastructure customers, all of which may have an adverse impact on our business, financial results, stock price and results of operations.

We may be adversely affected by the effects of inflation, including as a result of increased tariffs.

Inflation, including as a result of increased tariffs, has the potential to adversely affect our business, results of operations, financial position and liquidity by increasing our overall cost structure, particularly if we are unable to achieve commensurate increases in the prices we charge our customers. The existence of inflation in the economy has the potential to result in higher interest rates and capital costs, supply shortages, increased costs of labor and other similar effects. As a result of inflation, we may experience increases in the costs of labor, materials, and other

inputs, such as engineering consultants. Although we may take measures to mitigate the impact of this inflation, if these measures are not effective our business, results of operations, financial position and liquidity could be materially adversely affected. Even if such measures are effective, there could be a difference between the timing of when these beneficial actions impact our results of operations and when the cost of inflation is incurred.

A variety of risks associated with operating our business and marketing our products internationally could materially adversely affect our business.

A significant amount of our business activity is outside of the United States. We face risks associated with our international operations, including possible unfavorable regulatory, pricing and reimbursement, political, tariffs, tax and labor conditions, which could harm our business. We are subject to numerous risks associated with international business activities, including, but not limited to:

- compliance with differing or unexpected regulatory requirements for our products;
- difficulties in staffing and managing foreign operations;
- in certain circumstances, including with respect to the commercialization of our product candidates in Europe, increased dependence on the commercialization efforts of our distributors or strategic partners;
- foreign government taxes, regulations and permit requirements;
- United States and foreign government tariffs, trade restrictions, price and exchange controls and other regulatory requirements;
- economic weakness, including inflation, natural disasters, war, events of terrorism or political instability in particular foreign countries;
- fluctuations in currency exchange rates, which could result in increased operating expenses and reduced revenues, and other obligations related to doing business in another country;
- compliance with tax, employment, immigration and labor laws, regulations and restrictions for employees living or traveling abroad;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- changes in diplomatic and trade relationships; and
- challenges in enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States.

These and other risks associated with our international operations may materially adversely affect our business, financial condition and results of operations.

Risks Related to Our Intellectual Property

Our ability to compete may decline if we do not adequately protect our proprietary rights.

There is the risk that our patents (both those owned by us and those in-licensed) may not provide a competitive advantage, including the risk that our patents expire before we obtain regulatory and marketing approval for one or more of our product candidates, particularly our in-licensed patents. Also, our competitors may develop products similar to ours using methods and technologies that are beyond the scope of our intellectual property rights. Composition of matter patents on APIs may provide protection for pharmaceutical products without regard to formulation, method of use, or other type of limitation. We do not have compound patent protection for the API in our MN-166 (ibudilast) and MN-001 (tipelukast) product candidates, although we do have patent protection for a

particular crystalline polymorph of MN-001 (tipelukast) and we have composition of matter protection on an analog of MN-166 (ibudilast). As a result, competitors that obtain the requisite regulatory approval will be able to offer products with the same API as found in our MN-166 (ibudilast) and MN-001 (tipelukast) product candidates so long as such competitors do not infringe any methods of use, methods of manufacture, formulation or, in the case of MN-001 (tipelukast), specific polymorph patents that we hold or have exclusive rights to through our licensors. For example, we currently rely on method of use patents for MN-166 (ibudilast) and MN-001 (tipelukast).

It is our policy to consult with our licensors in the maintenance of granted patents we have licensed and in their pursuit of patent applications that we have licensed, but each of our licensors generally remains primarily responsible for or in control of the maintenance of the granted patents. We have limited control, if any, over the amount or timing of resources that each licensor devotes on our behalf. As a result of this lack of control, we cannot be sure that our licensed patents will be maintained and that any additional patents will ever mature from our licensed applications. Issued U.S. patents require the payment of maintenance fees to continue to be in force. We typically rely on our licensors to do this and their failure to do so could result in the forfeiture of patents not timely maintained. Many foreign patent offices also require the payment of periodic annuities to keep patents and patent applications in good standing. As we generally do not maintain control over the payment of annuities, we cannot be certain that our licensors will timely pay such annuities and that the granted patents will not become abandoned. In addition, our licensors may have selected a limited amount of foreign patent protection, and therefore applications have not been filed in, and foreign patents may not have been perfected in, all commercially significant countries.

The patent protection of our product candidates and technology involves complex legal and factual questions. Most of our license agreements give us a right, but not an obligation, to enforce our patent rights. To the extent it is necessary or advantageous for any of our licensors' cooperation in the enforcement of our patent rights, we cannot control the amount or timing of resources our licensors devote on our behalf or the priority they place on enforcing our patent rights. We may not be able to protect our intellectual property rights against third party infringement, which may be difficult to detect, especially for infringement of patent claims for methods of manufacturing. Additionally, challenges may be made to the ownership of our intellectual property rights, our ability to enforce them or our underlying licenses, which in some cases have been made under foreign laws and may provide different protections than that of U.S. law.

We cannot be certain that any of the patents or patent applications owned by us or our licensors related to our product candidates and technology will provide adequate protection from competing products. Our success will depend, in part, on whether we or our licensors can:

- obtain and maintain patents to protect our product candidates;
- obtain and maintain any required or desirable licenses to use certain technologies of third parties, which may be protected by patents;
- protect our trade secrets and know-how;
- operate without infringing the intellectual property and proprietary rights of others;
- enforce the issued patents under which we hold rights; and
- develop additional proprietary technologies that are patentable.

The degree of future protection for our proprietary rights is uncertain. For example:

- we or our licensor might not have been the first to make the inventions covered by each of our pending patent applications or issued patents;
- we or our licensor might not have been the first to file patent applications for these inventions;

- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- it is possible that none of our pending patent applications will result in issued patents;
- any patents under which we hold rights may not provide us with a basis for maintaining market exclusivity for commercially viable products, may not provide us with any competitive advantages or may be challenged by third parties as invalid, not infringed or unenforceable under United States or foreign laws; or
- any of the issued patents under which we hold rights may not be valid or enforceable or may be circumvented successfully in light of the continuing evolution of domestic and foreign patent laws.

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

As in the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is therefore costly, time-consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs. Recent patent reform legislation in the U.S. and other countries, including the Leahy-Smith America Invents Act (Leahy-Smith Act), signed into law on September 16, 2011, could increase those uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. These include allowing third party submission of prior art to the U.S. Patent and Trademark Office (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. After March 2013, under the Leahy-Smith Act, the United States transitioned to a first inventor to file system in which, assuming that the other statutory requirements are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

The United States Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. Depending on future actions by the United States Congress, the United States courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

The United States federal government retains certain rights in inventions produced with its financial assistance under the Bayh-Dole Act of 1980 (Bayh-Dole Act). The federal government retains a nonexclusive, nontransferable, irrevocable, paid-up license for its own benefit. The Bayh-Dole Act also provides federal agencies with "march-in rights". March-in rights allow the government, in specified circumstances, to require the contractor or successors in title to the patent to grant a nonexclusive, partially exclusive, or exclusive license to a responsible applicant or applicants. If the patent owner refuses to do so, the government may grant the license itself. If, in the future, we co-own or license in technology that is critical to our business that is developed in whole or in part with federal funds subject to the Bayh-Dole Act, our ability to enforce or otherwise exploit patents covering such technology may be adversely affected.

Additionally, the new unitary patent system that came into effect in Europe in June 2023 has increased the complexity and uncertainty of European patent laws and would significantly impact European patents, including those granted before the introduction of such a system. 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 Unitary Patent Court (UPC). As the UPC is a new court system, there is no precedent for the court, increasing the

uncertainty of any litigation. Patents granted before the implementation of the UPC will have the option of opting out of the jurisdiction of the UPC 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. We cannot predict with certainty the long-term effects of any potential changes.

Confidentiality agreements with employees and others may not adequately prevent disclosure of our trade secrets and other proprietary information and may not adequately protect our intellectual property, which could limit our ability to compete.

Because we operate in the highly technical field of research and development of small molecule drugs, we rely in part on trade secret protection in order to protect our proprietary trade secrets and unpatented know-how. However, trade secrets are difficult to protect, and we cannot be certain that others will not develop the same or similar technologies on their own. We have taken steps, including entering into confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors, to protect our trade secrets and unpatented know-how. These agreements generally require that the other party keep confidential and not disclose to third parties all confidential information developed by the party or made known to the party by us during the course of the party's relationship with us. We also typically obtain agreements from these parties which provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, these agreements may not be honored and may not effectively assign intellectual property rights to us. Further, we have limited control, if any, over the protection of trade secrets developed by our licensors. Enforcing a claim that a party illegally obtained and is using our trade secrets or know-how is difficult, expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States may be less willing to protect trade secrets or know-how. The failure to obtain or maintain trade secret protection could adversely affect our competitive position.

A dispute concerning the infringement or misappropriation of our proprietary rights or the proprietary rights of others could be time consuming and costly, and an unfavorable outcome could harm our business.

There is significant litigation in our industry regarding patent and other intellectual property rights. While we are not currently subject to any pending intellectual property litigation, and are not aware of any such threatened litigation, we may be exposed to future litigation by third parties based on claims that our product candidates, their methods of use, manufacturing or other technologies or activities infringe the intellectual property rights of such third parties. There are many patents relating to chemical compounds and methods of use. If our compounds or their methods of use or manufacture are found to infringe any such patents, we may have to pay significant damages or seek licenses under such patents. We have not conducted comprehensive searches for unexpired patents issued to third parties relating to our product candidates. Consequently, no assurance can be given that unexpired, third party patents containing claims covering our product candidates, their methods of use or manufacture do not exist. Moreover, because some patent applications in the United States may be maintained in secrecy until the patents are issued, and because patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, we cannot be certain that others have not filed patent applications that will mature into issued patents that relate to our current or future product candidates and which could have a material effect in developing and commercializing one or more of our product candidates. The owner of a patent that is arguably infringed can bring a civil action seeking to enjoin an accused infringer from importing, making, marketing, distributing, using or selling an infringing product. We may need to resort to litigation to enforce our intellectual property rights or to seek a declaratory judgment concerning the scope, validity or enforceability of third party proprietary rights. Similarly, we may be subject to claims that we have inappropriately used or disclosed trade secrets or other proprietary information of third parties. If we become involved in litigation, it could consume a substantial portion of our managerial and financial resources, regardless of whether we win or lose. Some of our competitors may be able to sustain the costs of complex intellectual property litigation more effectively than we can because they have substantially greater resources. We may not be able to afford the costs of litigation. Any legal action against us or our collaborators could lead to:

- payment of actual damages, royalties, lost profits, potential enhanced damages and attorneys' fees, if any infringement for which we are found liable is deemed willful, or a case against us is determined by a judge to be exceptional;

- injunctive or other equitable relief that may effectively block our ability to further develop, commercialize and sell our products;

- having to enter into license arrangements that may not be available on reasonable or commercially acceptable terms; or

- significant cost and expense, as well as distraction of our management from our business.

As a result, we could lose our ability to develop and commercialize current or future product candidates.

We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

As is common in the biotechnology and pharmaceutical industry, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. From time to time, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

Risks Related to the Securities Markets and Investment in Our Common Stock

The stock price of our common stock may be volatile or decline regardless of our operating performance, and you may not be able to resell our shares at a profit or at all.

Despite the listing of our common stock on the Nasdaq Global Market and the TSE in Japan, trading volume in our securities has been light and an active trading market may not develop for our common stock. In 2025, our average trading volume was approximately 268,522 shares per day on Nasdaq and approximately 112,544 shares per day on the TSE.

The market prices for securities of biopharmaceutical and biotechnology companies, and early-stage drug discovery and development companies like us in particular, have historically been highly volatile and may continue to be highly volatile in the future. For example, since the date of our initial public offering in Japan on February 8, 2005 through December 31, 2025, our common stock has traded as high as approximately $42.00 and as low as approximately $1.13. The following factors, in addition to other risk factors described in this section, may have a significant impact on the market price of our common stock, many of which are beyond our control:

- the development status of our product candidates, including clinical trial results and determinations by regulatory authorities with respect to our product candidates;

- the initiation, termination, or reduction in the scope of any collaboration arrangements or any disputes or developments regarding such collaborations;

- FDA or foreign regulatory actions, including failure to receive regulatory approval for any of our product candidates;

- announcements of technological innovations, new commercial products or other material events by us or our competitors;

- disputes or other developments concerning our intellectual property rights;

- market conditions in the pharmaceutical and biotechnology sectors;

- actual and anticipated fluctuations in our quarterly or annual operating results;

- price and volume fluctuations in the overall stock markets;
- changes in, or failure to meet, securities analysts' or investors' expectations of our financial performance;
- additions or departures of key personnel;
- the economy as a whole and market conditions in our industry;
- discussions of our business, management, products, financial performance, prospects or stock price by the financial and scientific press and online investor communities;
- litigation or public concern about the safety of our potential products;
- public concern as to, and legislative action with respect to, the pricing and availability of prescription drugs or the safety of drugs and drug delivery techniques; or
- regulatory developments in the United States and in foreign countries.

Broad market and industry factors, as well as economic and political factors, also may materially adversely affect the market price of our common stock.

Our common stock may be delisted from the Nasdaq Global Market or the Standard Market of the Tokyo Stock Exchange.

In addition to the risks identified immediately above, the market price of our common stock, and your ability to sell your shares at a profit, or at all, may be affected by the delisting of our shares for failure to meet applicable listing standards. For example, price per share minimums are maintained by the Nasdaq Global Market, and our share price has, in the past, fallen below the required minimum. Failure to meet these or other listing requirements for either of the stock exchanges on which our common stock is listed could adversely affect the market price for our common stock and your ability to sell your shares at a profit, or at all.

We may become involved in securities class action litigation that could divert management's attention and harm our business.

The stock markets have from time to time experienced significant price and volume fluctuations that have affected the market prices for the common stock of biotechnology and biopharmaceutical companies. These broad market fluctuations may cause the market price of our common stock to decline. 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 and biopharmaceutical companies have in the past experienced significant stock price volatility. We may become involved in this type of litigation in the future. Litigation often is expensive and diverts management's attention and resources, which could adversely affect our business.

Future sales of our common stock may cause our stock price to decline and may make it difficult for us to raise additional capital or for you to sell your shares.

Sales of substantial amounts of our common stock through our Standby Equity Purchase Agreement with YA II PN, LTD, our Equity Distribution Agreement with Lucid Capital Markets, LLC or otherwise, or the availability of such common stock for sale, could adversely affect the prevailing market prices for our common stock. If this occurs and continues, it could impair our ability to raise additional capital through the sale of securities if we should desire to do so. In addition, it may be difficult, or even impossible, to find a buyer for shares of our common stock.

We have also registered all common stock that we may issue under our current employee benefits plans. As a result, these shares can be freely sold in the public market upon issuance, subject to the terms of the underlying agreements governing the grants and the restrictions of the securities laws. In addition, our directors and officers may in the future establish programmed selling plans under Rule 10b5-1 of the Exchange Act, for the purpose of

effecting sales of our common stock. If any of these events cause a large number of our shares to be sold in the public market, the sales could reduce the trading price of our common stock and impede our ability to raise future capital.

If our estimates or judgments relating to our critical accounting policies are based on assumptions that change or prove to be incorrect, our results of operation could fall below the expectations of securities analysts and investors, resulting in a decline in the market price of our common stock.

The preparation of financial statements in conformity with U.S. generally accepted accounting principles (U.S. GAAP) requires management to make estimates and assumptions that affect the amounts reported in our financial statements and accompanying notes. We base our estimates on historical experience and estimates and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets, liabilities, equity, revenue and expenses that are not readily apparent from other sources. For example, as of December 31, 2025, we performed a qualitative impairment assessment of goodwill and indefinite-lived intangible assets which included an evaluation of changes in industry, market, and macroeconomic conditions as well as consideration of our financial performance and any significant trends. If we experience a sustained decline in our stock price or other material changes in the significant assumptions that affect the determination of the fair value of our single reporting unit, it may result in a goodwill and/or intangible asset impairment charge in future periods, and such charge may be material.

If our assumptions underlying our estimates and judgments relating to our critical accounting policies change or if actual circumstances differ from our assumptions, estimates or judgments, our operating results may be adversely affected and could fall below the expectations of securities analysts and investors, resulting in a decline in the market price of our common stock.

We are a "smaller reporting company" and may take advantage of certain scaled disclosures available to us. We cannot be certain if the reduced reporting requirements applicable to smaller reporting companies will make our common stock less attractive to investors.

We are a "smaller reporting company" as defined in the Exchange Act. As a smaller reporting company, we are permitted to comply with scaled disclosure obligations in our SEC filings as compared to other issuers who are not smaller reporting companies, including with respect to disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We have elected to adopt the accommodations available to smaller reporting companies. Until we cease to be a smaller reporting company, the scaled disclosure in our SEC filings will result in less information about our company being available than for public companies that are not smaller reporting companies.

We will be able to take advantage of these scaled disclosures for so long as our voting and non-voting common stock held by non-affiliates is less than $250 million measured on the last business day of our second fiscal quarter, or (ii) our annual revenue is less than $100 million during the most recently completed fiscal year and the market value of our voting and non-voting common stock held by non-affiliates is less than $700 million as measured on the last business day of our second fiscal quarter.

We cannot predict if investors will find our common stock less attractive because we will rely on certain scaled disclosures that are available to smaller reporting companies. 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.

Anti-takeover provisions in our charter documents and under Delaware law may make an acquisition of us more complicated and the removal and replacement of our directors and management more difficult.

Our restated certificate of incorporation and amended and restated bylaws contain provisions that may delay or prevent a change in control, discourage bids at a premium over the market price of our common stock or adversely affect the market price of our common stock and the voting and other rights of the holders of our common stock. These provisions may also make it difficult for stockholders to remove and replace our board of directors and management. These provisions:

- establish that members of our board of directors may be removed only for cause upon the affirmative vote of stockholders owning at least a majority of our capital stock;
- authorize the issuance of "blank check" preferred stock that could be issued by our board of directors in a discriminatory fashion designed to increase the number of outstanding shares and prevent or delay a takeover attempt;
- limit who may call a special meeting of stockholders;
- establish advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings;
- prohibit our stockholders from making certain changes to our restated certificate of incorporation or amended and restated bylaws except with 66-2/3% stockholder approval; and
- provide for a classified board of directors with staggered terms.

We also may be subject to provisions of the Delaware corporation law that, in general, prohibit any business combination with a beneficial owner of 15% or more of our common stock for three years unless the holder's acquisition of our stock was approved in advance by our board of directors. Although we believe these provisions collectively provide for an opportunity to receive higher bids by requiring potential acquirers to negotiate with our board of directors, they would apply even if the offer may be considered beneficial by some stockholders. In any

event, these provisions may delay or prevent a third party from acquiring us. Any such delay or prevention could cause the market price of our common stock to decline.

Item 1B. Unresolved Staff Comments

Not applicable.

Item 1C. Cybersecurity

We continue to augment the capabilities of our people, processes, and technologies in order to address our cybersecurity risks. Our cybersecurity risks, and the controls designed to mitigate those risks, are integrated into our overall risk management governance and are reviewed yearly by our board of directors.

Risk Management and Strategy

As of December 31, 2025, we have implemented a set of comprehensive cybersecurity and data protection policies and procedures. Risks from cybersecurity threats are regularly evaluated as a part of our broader risk management activities and as a fundamental component of our internal control system. Our employees and contractors receive annual cybersecurity awareness trainings, including specific topics related to social engineering and email frauds. We have capable employees and consultants with significant expertise in cybersecurity related to our industry. We invest in advanced technologies for continuous cybersecurity monitoring across our information technology environment which are designed to prevent, detect, and minimize cybersecurity attacks, as well as alert management of such attacks.

Our Information Technology General Controls are firmly established based on recognized industry standards and cover areas such as risk management, data backup, and disaster recovery. We have utilized an outsourced information technology consultant to reduce and monitor security threats and vulnerabilities and respond to all cybersecurity incidents affecting us, including prompt escalation and communication of major security incidents to senior business leadership and our board of directors.

Governance

Our board of directors is responsible for overseeing our cyber security risk management and strategy. Our senior leadership, including our Chief Executive Officer and Chief Financial Officer, regularly meets with and provides periodic briefings to our board of directors regarding our cybersecurity risks and activities, including any recent cybersecurity incidents and related responses, cybersecurity systems testing, activities of third parties, and the like.

Cybersecurity Threat Disclosure

To date, we are not aware of any cybersecurity threats that have materially affected or are reasonably likely to materially affect the Company.

For further discussion of cybersecurity risks, please see Item 1A, "Risk Factors".

Item 2. Properties

In December 2017, we executed a sublease agreement for our San Diego headquarters (Sublease) with Cardinal Health 127 Inc., the sublessor, to which Irvine Company, the master lessor, had provided its consent. The Sublease was for approximately 4,400 square feet and had a term of four years and one month. We have extended this Sublease for an additional 5 years through January 31, 2027.

In June 2005, we leased office space in Tokyo, Japan under a non-cancelable operating lease with an original expiration date of May 2013 and an auto-renewal two-year extension. The lease was renewed in May 2023 and has a term of two years with an auto-renewal, two year extension. In April 2024, we provided notice to terminate the previous lease agreement, effective October 2024, and in May 2024, we entered into a new lease agreement, effective June 2024, for a different office space for the Tokyo location. The new lease has an initial lease term of 12 months ending May 2025 with an option to extend for an additional two months, after which there will be automatic two-month renewals until the lease is terminated.

We have no laboratory, research or manufacturing facilities, and we currently do not plan to purchase or lease any such facilities, as such services are provided to us by third party service providers. We believe that our current facilities are adequate for our needs for the immediate future and that, should it be needed, suitable additional space will be available to accommodate expansion of our operations on commercially reasonable terms.

Item 3. Legal Proceedings

We are not involved in any material legal proceedings as of the date of this report. We may become involved in various disputes and legal proceedings which arise in the ordinary course of business. Our assessment of the likely impact of our pending litigation may change over time. An adverse result in any of these matters may occur which could harm our business and result in a material liability.

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 is listed on the Standard Market of the Tokyo Stock Exchange and trades under the code "4875," and is listed on the Nasdaq Global Market and trades under the symbol "MNOV."

Holders of Common Stock

As of March 5, 2026, there were approximately 10 holders of record of our common stock. Because many of our shares of common stock are held by brokers or other institutions on behalf of stockholders, we are unable to estimate the total number of stockholders represented by the record holders.

Dividend Policy

We have never declared or paid any cash dividends on our capital stock, and we do not anticipate paying any cash dividends in the foreseeable future. We expect to retain our future earnings, if any, to fund the growth and development of our business.

Securities Authorized for Issuance Under Equity Compensation Plans

Information regarding the securities authorized for issuance under our equity compensation plans can be found under Item 12 of this Annual Report on Form 10-K.

Unregistered Sales of Equity Securities and Use of Proceeds

None.

Purchases of Equity Securities by the Issuer and Affiliated Purchases

None.

Item 6. [Reserved.]

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

You should read the following discussion and analysis together with the consolidated financial statements and related notes included elsewhere in this Annual Report on Form 10-K. The following discussion contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those expressed or implied in any forward-looking statements as a result of various factors, including those set forth under the caption "Item 1A. Risk Factors."

Overview

Background

We are a biopharmaceutical company focused on developing novel therapeutics for the treatment of serious diseases with unmet medical needs and a commercial focus on the United States market. Our current strategy is to focus our development activities on MN-166 (ibudilast) for neurological and other disorders such as progressive multiple sclerosis (MS), amyotrophic lateral sclerosis (ALS), chemotherapy-induced peripheral neuropathy, degenerative cervical myelopathy, glioblastoma, and prevention of acute respiratory distress syndrome (ARDS), and MN-001 (tipelukast) for fibrotic and other metabolic disorders such as nonalcoholic fatty liver disease (NAFLD) and hypertriglyceridemia. We were incorporated in Delaware in September 2000.

We have incurred significant net losses since our inception. For the year ended December 31, 2025, we had a net loss of $12.0 million. At December 31, 2025, from inception, our accumulated deficit was $438.7 million. We expect to incur substantial net losses for the next several years as we continue to develop certain of our existing product development programs, and over the long-term if we expand our research and development programs and acquire or in-license products, technologies or businesses that are complementary to our own.

Upon completion of proof-of-concept Phase 2 clinical trials, we intend to discuss strategic alliances with leading pharmaceutical or biotechnology companies who seek late stage product candidates to support further clinical development and product commercialization. Depending on decisions we may make as to further clinical development, we may seek to raise additional capital. We may also pursue potential partnerships and potential acquirers of license rights to our programs in markets outside the United States.

Critical Accounting Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States (GAAP). The preparation of the consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses and the related disclosure of contingent liabilities. We review our estimates on an ongoing basis, including those related to our significant accruals. We base our estimates on historical experience and on various other assumptions 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. Actual results may differ from these estimates.

Our significant accounting policies are more fully described in Note 1 to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K. Our most critical accounting estimates include research, development and patent expenses which impacts operating expenses, accrued liabilities, in-process research and development (IPR&D) and goodwill. We review our estimates and assumptions periodically and reflect the effects of revisions in the period in which they are deemed to be necessary. We believe that the following accounting policies are critical to the judgments and estimates used in preparation of our consolidated financial statements.

Clinical Trial Accruals

Our research, development and patents expenses consist primarily of license fees related to our product candidates, salaries and related employee benefits, costs associated with the preclinical and clinical development of our product development programs, costs associated with non-clinical activities, such as regulatory expenses, and pre-commercialization manufacturing development activities. We use external service providers to manufacture our compounds to be used in clinical trials and for the majority of the services performed in connection with the preclinical and clinical development of our product candidates. Research, development and patents expenses include

fees paid to consultants, contract research organizations, contract manufacturers and other external service providers, including professional fees and costs associated with legal services, patents and patent applications for our intellectual property. Internal research and development expenses include costs of compensation and other expenses for research and development personnel, supplies, facility costs and depreciation. We determine accrual estimates through reports from and discussions with applicable personnel and outside service providers as to the progress or state of completion of studies, or the services completed. Costs that are paid in advance of performance are deferred as a prepaid expense and recognized over the service period as the services are performed. Our estimates of accrued expenses as of each balance sheet date are based on the facts and circumstances known at the time. Although we do not expect our estimates to be materially different from amounts actually incurred, if our estimates of the status and timing of services performed differ from the actual status and timing of services performed, it could result in us reporting amounts that are too high or low in any particular period. To date, our accrued research, development and patent expenses have not differed significantly from the actual expenses incurred.

The following table summarizes our research, development and patent expenses for the periods indicated for each of our product development programs. To the extent that costs, including personnel costs, are not tracked to a specific product development program, such costs are included in the "Other R&D expense" category (in thousands):

	Year Ended December 31,	
	2025	2024
External development expense:		
MN-166	$ 4,622	$ 4,485
MN-001	703	455
Other	12	12
Total external development expense	5,337	4,952
R&D personnel expense	1,149	1,608
R&D facility and depreciation expense	64	62
Patent expense	412	413
Other R&D expense	193	160
Total research, development and patent expense	$ 7,155	$ 7,195

IPR&D and Goodwill

Amounts incurred related to IPR&D or asset purchases of IPR&D are expensed as incurred. Amounts allocated to IPR&D in connection with a business combination are recorded at fair value and are considered indefinite-lived intangible assets until completion or abandonment of the associated research and development efforts. During the period the assets are considered indefinite-lived, they will not be amortized but will be tested annually for impairment or more frequently if indicators of impairment exist. Goodwill is reviewed for impairment annually (as of December 31st) or more frequently if indicators of impairment exist.

As of December 31, 2025, we performed a qualitative impairment assessment of goodwill and indefinite-lived intangible assets which included an evaluation of changes in industry, market, and macroeconomic conditions as well as consideration of our financial performance and any significant trends. The qualitative assessment indicated that it was not more likely than not that goodwill and indefinite-lived intangible assets are impaired as of December 31, 2025. If we experience a sustained decline in our stock price or other material changes in the significant assumptions that affect the determination of the fair value of our single reporting unit, it may result in a goodwill and/or intangible asset impairment charge in future periods, and such charge may be material.

Recent Accounting Pronouncements

The impact of recent accounting pronouncements is described in Note 1 of our consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

Results of Operations

Comparison of the Years ended December 31, 2025 and 2024

Revenues

Revenues were $0.4 million and $0.0 million for the years ended December 31, 2025 and 2024, respectively. The increase of $0.4 million was due to revenue recognized under our agreement with Mayo Foundation for Medical Education and Research (Mayo), which was entered into in December 2024 and which began enrolling patients in March 2025, and under which principal services began in April 2025.

Cost of Services

Cost of services were $0.4 million and $0.0 million for the years ended December 31, 2025 and 2024, respectively. The increase of $0.4 million was due to the costs incurred related to our performance of services under the Mayo agreement.

Research, Development and Patent Expenses

Research, development and patent expenses were $7.2 million for both the years ended December 31, 2025 and 2024. While overall expense was relatively the same year over year, changes to the component costs included an increase of $0.6 million in MN-166 related expenses for a MRC-001 PK study and a degenerative cervical myelopathy (DCM) study, and an increase of $0.2 million in MN-001 clinical trial expenses, offset by a decrease of $0.8 million in MN-166 manufacturing costs, payroll costs and stock-based compensation expense.

General and Administrative

General and administrative expenses for the year ended December 31, 2025 increased by $0.7 million to $6.2 million compared to $5.5 million for the prior year, primarily driven by fees of $0.4 million related to the Standby Equity Purchase Agreement, or the SEPA, that we entered into in July 2025, and an increase of $0.5 million in professional and investor relation expenses, partially offset by decreased stock-based compensation expense of $0.2 million.

Interest Income

Interest income for the year ended December 31, 2025 decreased by $0.4 million to $1.3 million compared to $1.7 million for the prior year, primarily driven by a decrease in our cash balance generating interest. Interest income consists of interest earned on our cash and cash equivalents.

Liquidity and Capital Resources

We incurred losses of $12.0 million and $11 million for the years ended December 31, 2025 and 2024, respectively. At December 31, 2025, our accumulated deficit was $438.7 million as compared to $426.8 million for the year ended December 31, 2024. Our operating losses to date have been funded primarily through the private placement of our equity securities, the public sale of our common stock, long-term debt, development agreements with partners and the exercise of warrants, net of treasury stock repurchases.

The following table shows a summary of our cash flows for the years ended December 31, 2025 and 2024 (in thousands):

	2025	2024
Net cash (used in) provided by:		
Operating activities	$ (9,810)	$ (10,643)
Investing activities	(3)	(1)
Financing activities	244	—

Factors That May Affect Future Financial Condition and Liquidity

As of December 31, 2025, we had available cash and cash equivalents of $30.8 million and working capital of $27.2 million. As of the date of this report, we believe we have sufficient working capital to fund operations at least twelve months from the date these financial statements are issued. This is based on our expected operating cash needs for 2026 to be approximately $16.2 million and assuming we keep our spend at a similar level for 2027 including expected inflation increases. We expect that this level of operating spend will be sufficient to cover the research and development expenses needed to help monetize our product candidates in development.

Our future funding requirements will depend on many factors, including, but not limited to:

- progress in, and the costs of, future planned clinical trials and other research and development activities;
- the scope, prioritization and number of our product development programs;
- our obligations under our license agreements, pursuant to which we may be required to make future milestone payments upon the achievement of various milestones related to clinical, regulatory or commercial events;
- our ability to establish and maintain strategic collaborations, including licensing and other arrangements, and to complete acquisitions of additional product candidates;
- the time and costs involved in obtaining regulatory approvals;
- the costs of securing manufacturing arrangements for clinical or commercial production of our product candidates;
- the costs associated with any expansion of our management, personnel, systems and facilities;
- the costs associated with any litigation;
- the costs associated with the operations or wind-down of any business we may acquire;
- the costs involved in filing, prosecuting, enforcing and defending patent claims and other intellectual property rights; and
- the costs of establishing or contracting for sales and marketing capabilities and commercialization activities if we obtain regulatory approval to market any of our product candidates.

At December 31, 2025, we did not have any off balance sheet activity and we did not have any relationship with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance, variable interest, or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. In addition, we did not engage in trading activities involving non-exchange traded contracts. As a result, we are not exposed to any financing, liquidity, market or credit risk that could arise if we had engaged in such relationships. We do not have relationships and transactions with persons and entities that derive benefits from their non-independent relationship with us or our related parties except as disclosed herein.

Equity Financing

On August 26, 2022, we entered into an amendment to an at market issuance sales agreement (as amended, the "ATM Agreement") with B. Riley Securities, Inc. (formerly B. Riley FBR, Inc.) (B. Riley Securities) for the offer and sale of common stock through B. Riley Securities from time to time up to an aggregate offering price of $75.0 million.

No shares of common stock were sold under the ATM Agreement for the years ended December 31, 2025 and December 31, 2024.

On February 26, 2026 we notified B. Riley Securities that we were terminating the ATM agreement effective as of March 8, 2026.

On July 30, 2025, we entered into a SEPA, with YA II PN, LTD., a Cayman Islands exempt limited company, or Yorkville. Pursuant to the SEPA, we have the right, but not the obligation, to sell to Yorkville from time to time up to $30.0 million of our common stock, during the 36 months following the execution of the SEPA, subject to the restrictions and satisfaction of the conditions in the SEPA. At our option, the shares of common stock would be purchased by Yorkville from time to time at a price equal to 97% of the lowest of the three daily volume weighted average prices (VWAPs), during a three consecutive trading day period commencing on the date that we, subject to certain limitations, deliver to Yorkville a notice that we are committing Yorkville to purchase such shares of common stock. We may also specify a certain minimum acceptable price per share for a drawdown under the SEPA. As consideration for Yorkville's irrevocable commitment to purchase common stock, we paid Yorkville a $25,000 structuring fee along with a commitment fee of $375,000, recorded as General and Administrative expense. Under the applicable rules of Nasdaq and pursuant to the SEPA, in no event may we issue or sell to Yorkville more than 9,804,345 shares of common stock, or the Exchange Cap, which is 19.99% of the shares of common stock outstanding immediately prior to the execution of the SEPA, unless (i) we obtain stockholder approval to issue shares of common stock in excess of the Exchange Cap or (ii) the average price of all applicable shares of common stock under the SEPA equals or exceeds $1.33 per share (which represents the lower of (i) the Nasdaq Official Closing Price (as reflected on Nasdaq.com) on the trading day immediately preceding July 30, 2025 or (ii) the average Nasdaq Official Closing Price of the common stock (as reflected on Nasdaq.com) for the five trading days immediately preceding July 30, 2025). Pursuant to the SEPA, Yorkville shall not be obliged to purchase or acquire any shares of common stock under the SEPA which, when aggregated with all other shares of our common stock beneficially owned by Yorkville and its affiliates, would result in the beneficial ownership of Yorkville and its affiliates (on an aggregated basis) exceeding 4.99% of the then outstanding voting power or number of outstanding shares of our common stock.

Pursuant to a financial advisory agreement between us and D. Boral Capital LLC (D. Boral), we have also agreed to pay D. Boral a fee equal to three percent of the gross proceeds received from any shares that we sell to Yorkville pursuant to the SEPA.

For the year ended December 31, 2025, we sold 175,000 shares of our common stock at prices ranging from $1.39 to $1.40 per share for proceeds of $0.2 million under the SEPA.

On December 29, 2025, we entered into an equity distribution agreement, with Lucid Capital Markets, LLC (Lucid) pursuant to which we may sell common stock through Lucid from time to time up to an aggregate offering price of $50.0 million (the Equity Distribution Agreement). Sales of our common stock through Lucid, if any, will be made by any method that is deemed to be an "at-the-market" equity offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended, including sales made directly on Nasdaq, on any other existing trading market for the common stock or through a market maker. Lucid may also sell the common stock in privately negotiated transactions, subject to our prior approval. We agreed to pay Lucid an aggregate commission rate of 3.0% of the gross proceeds of any common stock sold under this agreement. Proceeds from sales of common stock will depend on the number of shares of common stock sold to Lucid and the per share purchase price of each transaction.

No shares of common stock were sold under the Equity Distribution Agreement in the year ended December 31, 2025.

Contractual Obligations and Commitments

We have entered into arrangements that contractually obligate us to make payments that will affect our liquidity and cash flows in future periods. Such arrangements include those related to the contractual obligations described below:

Lease Commitments

Our operating lease commitments reflect payments due for our lease agreements in San Diego, California and Tokyo, Japan. As of December 31, 2025, our contractual commitments for our leases were $0.2 million, which will be paid over the lease terms.

Milestone Obligations

We have entered into in-licensing agreements with various pharmaceutical companies. Under the terms of these agreements, we have received licenses to research, know-how and technology claimed, in certain patents or patent applications. Under these license agreements, we are generally required to make upfront payments and additional payments upon the achievement of milestones and/or royalties on future sales of products until the later of the expiration of the applicable patent or the applicable last date of market exclusivity after the first commercial sale, on a country-by-country basis. Assuming the milestones are met, total future potential milestone payments aggregate to $26.5 million.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Not applicable.

Item 8. Financial Statements and Supplementary Data

Index to Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm

Shareholders and Board of Directors
MediciNova, Inc.
La Jolla, California

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of MediciNova, Inc. (the "Company") as of December 31, 2025 and 2024, the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for each of the years then ended, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2025 and 2024, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated 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 consolidated 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 consolidated 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 consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Clinical Trial Accruals

As described in Note 1 to the consolidated financial statements, the Company recognizes costs it incurs for preclinical studies, clinical trials and manufacturing activities as research and development expenses based on its evaluation of its vendors' progress toward completion of specific tasks. Payment timing may differ significantly from the period in which the costs are recognized as expense. Costs for services incurred that have not yet been billed or paid are recognized as accrued expenses. In estimating the vendors' progress toward completion of specific tasks, the Company uses data such as patient enrollment, milestones achieved, clinical site activations or vendor information of actual costs incurred. This data is obtained through reports from or discussions with Company personnel and outside service providers as to the progress or state of completion of trials, or the completion of services. As of December 31, 2025, the Company recorded $1.4 million in clinical trial accruals.

We identified clinical trial accruals as a critical audit matter due to management judgment used to estimate the progress toward completion of specific tasks that is dependent upon data and information from internal clinical personnel and outside service providers. Auditing these elements involved especially challenging auditor judgment due to the nature of audit evidence and extent of audit effort required to address these matters.

The primary procedures we performed to address this critical audit matter included:

- Testing the appropriate measurement of clinical trial accruals by:
    - Inspecting significant agreements and agreement amendments,
    - Evaluating the Company's documentation of trial progress and status (including consideration of measures such as patient enrollment and milestones achieved, clinical site activations or vendor information of actual costs incurred),
    - Testing a sample of transactions and comparing the costs against related invoices and contracts, and
    - Confirming certain amounts invoiced and paid as well as invoiced and unpaid directly with a service provider.
- Testing the completeness of the Company's clinical trial accruals by evaluating publicly available information (such as press releases and public databases that track clinical trials) and board of directors' materials regarding the status of clinical trials and inquiring of clinical staff to gain an understanding of the status of certain on-going clinical trials.
- Testing a sample of subsequent payments to evaluate the completeness of clinical trial accruals at the end of the year.

/s/ BDO USA, P.C.

We have served as the Company's auditor since 2015.

San Diego, California

March 10, 2026

MEDICINOVA, INC.

CONSOLIDATED BALANCE SHEETS

	December 31,	
	2025	2024
Assets:		
Current assets:		
Cash and cash equivalents	$ 30,806,477	$ 40,359,738
Prepaid expenses and other current assets	184,827	714,541
Total current assets	30,991,304	41,074,279
Goodwill	9,600,240	9,600,240
In-process research and development	4,800,000	4,800,000
Property and equipment, net	8,340	25,507
Right-of-use asset	184,229	356,904
Other non-current assets	18,996	18,996
Total assets	$ 45,603,109	$ 55,875,926
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 624,995	$ 1,102,494
Accrued liabilities and other current liabilities	2,608,021	1,662,860
Deferred revenue	370,160	—
Operating lease liability	194,331	193,769
Total current liabilities	3,797,507	2,959,123
Deferred tax liability	201,792	201,792
Other non-current liabilities	17,129	211,460
Total liabilities	4,016,428	3,372,375
Commitments and contingencies (Note 5)		
Stockholders' equity:		
Common stock, $0.001 par value; 100,000,000 shares authorized at December 31, 2025 and December 31, 2024; 49,221,246 and 49,046,246 shares issued and outstanding at December 31, 2025 and December 31, 2024, respectively	49,221	49,046
Additional paid-in capital	480,413,839	479,340,901
Accumulated other comprehensive loss	(127,180)	(135,154)
Accumulated deficit	(438,749,199)	(426,751,242)
Total stockholders' equity	41,586,681	52,503,551
Total liabilities and stockholders' equity	$ 45,603,109	$ 55,875,926

See accompanying notes to consolidated financial statements.

MEDICINOVA, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	Years ended December 31,	
	2025	2024
Revenues	$ 409,657	$ —
Operating expenses:		
Cost of services	378,606	—
Research, development and patents	7,154,848	7,194,731
General and administrative	6,159,205	5,480,600
Total operating expenses	13,692,659	12,675,331
Operating loss	(13,283,002)	(12,675,331)
Interest income	1,303,792	1,670,804
Other expense, net	(12,753)	(39,485)
Loss before income taxes	(11,991,963)	(11,044,012)
Income tax expense	(5,994)	(5,537)
Net loss	$ (11,997,957)	$ (11,049,549)
Basic and diluted net loss per common share	$ (0.24)	$ (0.23)
Shares used to compute basic and diluted net loss per common share	49,063,438	49,046,246
Net loss	$ (11,997,957)	$ (11,049,549)
Other comprehensive income (loss), net of tax:		
Foreign currency translation adjustments	7,974	(17,064)
Comprehensive loss	$ (11,989,983)	$ (11,066,613)

See accompanying notes to consolidated financial statements.

MEDICINOVA, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

	Common stock		Additional paid-in capital	Accumulated other comprehensive loss	Accumulated deficit	Total stockholders' equity
	Shares	Amount				
Balance at December 31, 2023	49,046,246	$ 49,046	$ 478,149,161	$ (118,090)	$ (415,701,693)	$ 62,378,424
Stock-based compensation	—	—	1,191,740	—	—	1,191,740
Net loss	—	—	—	—	(11,049,549)	(11,049,549)
Foreign currency translation adjustments	—	—	—	(17,064)	—	(17,064)
Balance at December 31, 2024	49,046,246	49,046	479,340,901	(135,154)	(426,751,242)	52,503,551
Stock-based compensation	—	—	829,095	—	—	829,095
Issuance of common stock under standby equity purchase agreement (SEPA)	175,000	175	243,843	—	—	244,018
Net loss	—	—	—	—	(11,997,957)	(11,997,957)
Foreign currency translation adjustments	—	—	—	7,974	—	7,974
Balance at December 31, 2025	49,221,246	$ 49,221	$ 480,413,839	$ (127,180)	$ (438,749,199)	$ 41,586,681

See accompanying notes to consolidated financial statements.

MEDICINOVA, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years ended December 31,	
	2025	**2024**
Operating activities:		
Net loss	$ (11,997,957)	$ (11,049,549)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash stock-based compensation	829,095	1,191,740
Depreciation and amortization	20,099	21,077
Gain on disposal of property and equipment	—	(198)
Change in carrying amount of right-of-use asset	173,681	173,522
Changes in assets and liabilities:		
Prepaid expenses and other assets	530,000	(491,005)
Accounts payable, accrued liabilities and other liabilities	459,871	(312,347)
Deferred revenue	370,160	—
Operating lease liabilities	(195,010)	(176,204)
Net cash used in operating activities	(9,810,061)	(10,642,964)
Investing activities:		
Proceeds from sale of property and equipment	—	198
Acquisitions of property and equipment	(2,899)	(895)
Net cash used in investing activities	(2,899)	(697)
Financing activities:		
Proceeds from issuance of equity under SEPA	244,018	—
Net cash provided by financing activities	244,018	—
Effect of exchange rate changes on cash and cash equivalents	15,681	3,957
Net change in cash and cash equivalents	(9,553,261)	(10,639,704)
Cash and cash equivalents, beginning of year	40,359,738	50,999,442
Cash and cash equivalents, end of year	$ 30,806,477	$ 40,359,738
Supplemental disclosure of cash flow information:		
Right-of-use asset obtained in exchange for operating lease liability	—	$ 42,281
Change in carrying amount of right-of-use asset due to termination of lease	—	$ 79,229
Income taxes paid	$ 5,619	$ 5,042

See accompanying notes to consolidated financial statements.

MEDICINOVA, INC.

Notes to Consolidated Financial Statements

1. Organization and Summary of Significant Accounting Policies

Organization and Business

MediciNova, Inc. (the Company or MediciNova) was incorporated in the state of Delaware in September 2000 and is a public company. The Company's common stock is listed in both the United States and Japan and trades on the Nasdaq Global Market and the Standard Market of the Tokyo Stock Exchange. The Company is a biopharmaceutical company focused on developing novel therapeutics for the treatment of serious diseases with unmet medical needs with a commercial focus on the United States market. The Company's current strategy is to focus its development activities on MN-166 (ibudilast) for neurological and other disorders such as progressive multiple sclerosis (MS), amyotrophic lateral sclerosis (ALS), chemotherapy-induced peripheral neuropathy, degenerative cervical myelopathy, glioblastoma, and prevention of acute respiratory distress syndrome (ARDS), and MN-001 (tipelukast) for fibrotic and other metabolic disorders such as nonalcoholic fatty liver disease (NAFLD) and hypertriglyceridemia.

Principles of Consolidation

The consolidated financial statements include the accounts of MediciNova, Inc. and its wholly owned subsidiaries MediciNova Japan, Inc., MediciNova (Europe) Limited, MediciNova Europe GmbH, MediciNova Canada, Inc. and Avigen Inc. The financial statements of the Company's foreign subsidiaries are measured using their local currency as the functional currency. The resulting translation adjustments are recorded as a component of other comprehensive income or loss. Intercompany transaction gains or losses at each period end are included as translation adjustments and recorded within other comprehensive income or loss. All intercompany transactions and balances are eliminated in consolidation.

Segment Reporting

An operating segment is identified as a component of an enterprise that engages in business activities about which separate discrete financial information and operating results is regularly reviewed by the chief operating decision-maker (CODM) in making decisions regarding resource allocation and assessing performance. The Company's CODM is the senior executive committee which is comprised of the Chief Executive Officer, Chief Medical Officer, and the Chief Financial Officer. The Company operates in a single operating segment – the acquisition and development of small molecule therapeutics for the treatment of serious diseases with unmet medical needs. The CODM assesses performance for the segment and decides how to allocate resources based on consolidated net loss as reported on the statement of operations, after taking into account the Company's strategic priorities, its cash balance, and its expected use of cash. Further, the CODM reviews and utilizes functional expenses (i.e., research, development, and patent expense, and general and administrative) at the consolidated level to manage the Company's operations. Other segment items included in consolidated net loss are revenues, stock-based compensation, depreciation and amortization, interest income, other expense, net, and income tax expense, which are reflected in the consolidated statements of operations and comprehensive loss. The measure of segment assets is reported on the consolidated balance sheet as total consolidated assets.

The following table presents financial information, including significant segment expenses, which are regularly provided to the CODM and included within segment and consolidated net loss:

	Year Ended December 31,	
	2025	2024
Revenues	$ 409,657	$ —
Operating expenses, excluding stock-based compensation		
Cost of services	378,606	—
Research, development and patents	6,849,996	6,751,167
General and administrative	5,634,962	4,732,424
Total operating expenses, excluding stock-based compensation	12,863,564	11,483,591
Stock-based compensation		
Research, development and patents	304,852	443,564
General and administrative	524,243	748,176
Total stock-based compensation	829,095	1,191,740
Total operating expenses	13,692,659	12,675,331
Operating loss	(13,283,002)	(12,675,331)
Interest income	1,303,792	1,670,804
Other expense, net	(12,753)	(39,485)
Income tax expense	(5,994)	(5,537)
Segment and consolidated net loss	$ (11,997,957)	$ (11,049,549)

Use of Estimates

The preparation of the consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Cash and Cash Equivalents

Cash and cash equivalents consist of cash and other highly liquid investments, including money market and mutual funds accounts, with original maturities of three months or less from the date of purchase.

Investments

Investments purchased with an original maturity of greater than three months are classified as investments. Investments are stated at fair value and are classified as current or non-current based on the nature of the securities as well as their stated maturities. There were no investments held as of December 31, 2025 and December 31, 2024, respectively.

Concentrations and Credit Risk

The Company maintains cash balances and has purchased certificates of deposit at various financial institutions and such balances and certificates of deposit commonly exceed the $250,000 amount insured by the Federal Deposit Insurance Corporation. The Company also maintains money market and mutual funds at various financial institutions which are not federally insured although are invested primarily in U.S. government securities. The Company has not experienced any losses in such accounts and management believes that the Company does not have significant credit risk with respect to such cash and cash equivalents.

Fair Value of Financial Instruments

Financial instruments, including cash equivalents and accounts payable, are carried at cost, which management believes approximates fair value because of the short-term nature of these instruments.

IPR&D, Long-Lived Assets and Goodwill

Amounts incurred related to in-process research and development (IPR&D) or asset purchases of IPR&D are expensed as incurred. Amounts allocated to IPR&D in connection with a business combination are recorded at fair

value and are considered indefinite-lived intangible assets until completion or abandonment of the associated research and development efforts. If and when development is complete, which generally occurs when regulatory approval to market a product is obtained, the associated assets are deemed finite-lived and amortized over a period that best reflects the economic benefits provided by these assets. During the period the assets are considered indefinite-lived, they will not be amortized but will be tested annually for impairment or more frequently if indicators of impairment exist. The Company first assesses qualitative factors to determine whether it is more likely than not that the fair value of the IPR&D is less than its carrying amount as a basis for determining whether it is necessary to perform a quantitative assessment. If, after assessing qualitative factors, the Company determines it is not more likely than not that the fair value is less than its carrying amount, then a quantitative assessment is unnecessary. If the quantitative assessment is deemed necessary, the excess of the carrying value over fair value will be recorded as an impairment. The qualitative assessment focuses on the key inputs, assumptions and rationale utilized in the establishment of the carrying value and related changes since the last quantitative assessment. Based on the results of the Company's annual qualitative assessment, the Company concluded that it is not more likely than not that IPR&D was impaired for any of the periods presented.

The Company's long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying value may not be recoverable, and the Company will perform an impairment analysis. The Company has a single asset group. Long-lived assets are deemed to be impaired when the undiscounted cash flows expected to be generated are less than the asset's carrying amount. Any required impairment loss would be measured as the amount by which the asset's carrying value exceeds its fair value and would be recorded as a reduction in the carrying value of the related asset and a charge to operating expense. There were no events or changes in circumstances to indicate that the carrying value may not be recoverable for any of the periods presented.

Goodwill is reviewed for impairment annually (as of December 31st) or more frequently if indicators of impairment exist. As the Company operates in a single operating segment and reporting unit, goodwill is assessed at a consolidated level. The Company first assesses qualitative factors to determine whether it is more likely than not that the fair value of the reporting unit is less than its carrying amount, including goodwill. If so, the Company will proceed with a quantitative assessment that compares the fair value of the reporting unit with its carrying amount. If the fair value exceeds the carrying value as a result of either the qualitative or quantitative test, goodwill is not considered impaired. The qualitative factors include economic environment, business climate, market capitalization, operating performance, competition, and other factors. The Company placed the highest weight in excess cushion of the market capitalization to the equity carrying value in the analysis. Based on the results of the Company's annual qualitative assessment, the Company concluded that it is not more likely than not that goodwill was impaired for any of the periods presented.

Research, Development and Patents

Research and development costs are expensed in the period incurred. Research and development costs primarily consist of salaries and related expenses for personnel, facilities and depreciation, research and development supplies, licenses and outside services. Such research and development costs totaled $6.7 million and $6.8 million for the years ended December 31, 2025 and 2024, respectively.

Costs related to filing and pursuing patent applications are expensed as incurred, as recoverability of such expenditures is uncertain. The Company includes all external costs related to the filing of patents in Research, Development and Patents expenses. Such patent-related expenses totaled $0.4 million and $0.4 million for the years ended December 31, 2025 and 2024, respectively.

Leases

The Company determines if an arrangement is a lease at inception and if so, determines whether the lease qualifies as an operating or finance lease. The Company does not recognize right-of-use assets and lease liabilities for leases with a term of 12 months or less and does not separate non-lease components from lease. Operating lease right-of-use assets and liabilities are recognized at commencement date based on the present value of lease payments over the lease term. Operating lease expense is recognized on a straight-line basis over the lease term and is included in general and administrative expense. As the Company's operating leases do not provide an implicit rate, the Company uses its incremental borrowing rate based on the information available at commencement date in determining the present value of lease payments. The incremental borrowing rate is the rate that the Company would

expect to pay to borrow on a collateralized and fully amortizing basis over a similar term an amount equal to the lease payments in a similar economic environment.

Clinical Trial Accruals and Prepaid Expenses

Costs for preclinical studies, clinical studies and manufacturing activities are recognized as research and development expenses based on an evaluation of the progress by Company vendors towards completion of specific tasks, using data such as patient enrollment, milestones achieved, clinical site activations or information provided to the Company by such vendors regarding their actual costs incurred. Payments for these activities are based on the terms of individual contracts and payment timing may differ significantly from the period in which the services are performed. The Company determines accrual estimates through reports from and discussions with applicable personnel and outside service providers as to the progress or state of completion of studies, or the services completed. The Company's estimates of accrued expenses as of each balance sheet date are based on the facts and circumstances known at the time. Costs that are paid in advance of performance are deferred as a prepaid expense and recognized over the service period as the services are provided. As of December 31, 2025, the Company recorded $1.4 million and $0.1 million in clinical trial accruals and prepaid expenses, respectively. As of December 31, 2024, the Company recorded $0.7 million and $0.5 million in clinical trial accruals and prepaid expenses, respectively.

Stock-Based Compensation

The Company estimates the fair value of stock options using the Black-Scholes option pricing model on the date of grant. The fair value of equity instruments expected to vest are recognized and amortized on a straight-line basis over the requisite service period of the award, which is generally one to three years; however, the Company's equity compensation plans provide for any vesting schedule as the board may deem appropriate. Forfeitures are recognized as they occur.

The Company issues employee performance-based stock options, the vesting of which is based on a determination made by the board of directors as to the achievement of certain corporate objectives at the end of the performance period. The grant date of such awards is the date on which the board of directors makes its determination. For periods preceding the grant date, the expense related to these awards is measured based on their fair value at each reporting date and the expected number of options based upon the expected performance compared to the performance objectives.

Income Taxes

Income taxes are determined using the asset and liability approach of accounting for income taxes. Under this approach, deferred taxes represent the future tax consequences expected to occur when the reported amounts of assets and liabilities are recovered or paid. Deferred taxes result from differences between the financial statement and tax bases of assets and liabilities and are adjusted for changes in tax rates and tax laws when changes are enacted. A valuation allowance is recorded to reduce deferred tax assets when it is more likely than not that a tax benefit will not be realized. The Company's policy is to recognize interest expense and penalties related to income tax matters as tax expense.

Net Loss Per Share

The Company computes basic net loss per share using the weighted average number of common shares outstanding during the period. Diluted net loss per share is based upon the weighted average number of common shares and potentially dilutive securities (common share equivalents) outstanding during the period. Common share equivalents outstanding, determined using the treasury stock method, are comprised of shares that may be issued under the Company's outstanding stock option agreements. Common share equivalents are excluded from the diluted net loss per share calculation if their effect is anti-dilutive.

Potentially dilutive outstanding securities of 8,002,394 and 7,040,894 consisting of stock options for the years ended December 31, 2025 and 2024, respectively, were excluded from diluted net loss per common share because of their anti-dilutive effect.

Recently Issued Accounting Pronouncements

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures.* ASU 2023-09 enhances the transparency and decision usefulness of income tax disclosures. Specifically, it requires that a public business entity: 1) disclose, on an annual basis, an income tax rate reconciliation in a tabular form, disclosing specific categories and providing additional information for reconciling items that meet a quantitative threshold; 2) disclose on an annual basis the following information about income taxes paid: i) the amount of income taxes paid (net of refunds received) disaggregated by federal (national), state, and foreign taxes, ii) the amount of income taxes paid (net of refunds received) disaggregated by individual jurisdictions in which income taxes paid (net of refunds received) is equal to or greater than 5 percent of total income taxes paid (net of refunds received); 3) all entities are required to disclose: i) income (or loss) from continuing operations before income tax expense (or benefit) disaggregated between domestic and foreign; and ii) income tax expense (or benefit) from continuing operations disaggregated by federal (national), state, and foreign. For public business entities, the amendments are effective for annual periods beginning after December 15, 2024. For all other entities, the amendments are effective for annual periods beginning after December 15, 2025. Early adoption is permitted for annual financial statements that have not yet been issued or made available for issuance. The amendments in this ASU should be applied on a prospective basis. Retrospective application is permitted. The Company adopted ASU 2023-09 on January 1, 2025 using the retrospective method for the comparative period with additional disclosure contained in Note 8, *Income Taxes*.

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.* ASU 2024-03 requires additional disclosure of the nature of expenses included in the financial statements. ASU 2024-03 is effective for fiscal years beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027. Early adoption is permitted. The Company is currently evaluating the potential impact that this standard will have on its consolidated financial statements and related disclosures.

2. Revenue Recognition

Revenue Recognition Policy

Revenues historically have consisted mainly of research and development services performed under contracts with customers. The Company evaluates the separate performance obligation(s) under each contract, allocates the transaction price to each performance obligation considering the estimated stand-alone selling prices of the services and recognizes revenue upon the satisfaction of such obligations at a point in time or over time dependent on the satisfaction of one of the following criteria: (1) the customer simultaneously receives and consumes the economic benefits provided by the vendor's performance; (2) the vendor creates or enhances an asset controlled by the customer; (3) the vendor's performance does not create an asset for which the vendor has an alternative use; and (4) the vendor has an enforceable right to payment for performance completed to date.

Mayo Foundation for Medical Education and Research

In December 2024, the Company entered into an agreement with Mayo Foundation for Medical Education and Research (Mayo), to support clinical research services to evaluate the efficacy of MN-166 (ibudilast) in ALS. The agreement had an initial one year term, with automatic successive one year terms unless either party gives written notice of non-renewal to the other party not less than 90 days prior to the end of the then-current term, with payment for services due within 60 days from invoice. The agreement can be terminated by either party upon the occurrence of certain events, including by either party, without cause, upon not less than 30 days prior written notice. In August 2025, the Mayo agreement was amended to extend the initial term until August 2026. The Company assessed the services in accordance with the authoritative guidance and concluded that it met the definition of a contract per ASC 606 with one performance obligation. The performance obligation identified was for pharmacovigilance and clinical research support services satisfied over time using the cost-to-cost method. In March 2025, the first study site enrolled the first patients into the study and principal services under the agreement began in April 2025. In August 2025, the Company received $0.8 million from Mayo, of which $0.4 million is a current liability recognized as deferred revenue as of December 31, 2025. The Company recognized revenue of $0.4 million in the year ended December 31, 2025. The remaining performance obligation under this agreement relates to pharmacovigilance and

clinical research support services, which will be satisfied over the remaining term of the agreement. As of December 31, 2025, the aggregate amount of the transaction price allocated to remaining performance obligations was $1.8 million, of which approximately 31% is expected to be converted to revenue in 2026, 31% in the following twelve months, and the remainder thereafter.

3. Fair Value Measurements

Fair value is an 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 such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, a three-tier fair value hierarchy has been established, which prioritizes the inputs used in measuring fair value as follows:

Level 1: Observable inputs such as quoted prices in active markets;

Level 2: Inputs are quoted prices for similar items in active markets or inputs are quoted prices for identical or similar items in markets that are not active near the measurement date; and

Level 3: Unobservable inputs due to little or no market data, which require the reporting entity to develop its own assumptions.

The carrying amount and approximate fair value of financial instruments as of December 31, 2025 and 2024, were as follows:

	December 31, 2025		December 31, 2024		
	Carrying Amount	Fair Value	Carrying Amount	Fair Value	Valuation Inputs
Cash equivalents:					
Mutual funds	$ 30,308,988	$ 30,308,988	$ 21,501,081	$ 21,501,081	Level 1

4. Balance Sheet Details

Property and Equipment

Property and equipment, net, consist of the following:

	December 31,	
	2025	2024
Furniture and equipment	$ 88,521	$ 85,613
Software	342,628	342,628
	431,149	428,241
Less accumulated depreciation and amortization	(422,809)	(402,734)
Property and equipment, net	$ 8,340	$ 25,507

The Company uses the straight-line method to record depreciation expense with useful lives of three to five years. Depreciation and amortization of property and equipment of $20,099 and $21,077 was recorded for the years ended December 31, 2025 and 2024, respectively.

Accrued Liabilities and Other Current Liabilities

Accrued liabilities and other current liabilities consist of the following:

	December 31,	
	2025	2024
Accrued compensation	$ 824,529	$ 785,949
Clinical trial accruals	1,368,949	726,130
Professional services fees	268,003	23,949
Other	146,540	126,832
Total accrued liabilities and other current liabilities	$ 2,608,021	$ 1,662,860

5. Commitments and Contingencies

Lease Commitments

The Company has operating leases primarily for real estate in the United States and Japan. The United States lease is for the Company's headquarters in San Diego and has a term of five years ending January 31, 2027, with annual escalations. In April 2024, the Company provided notice to terminate its previous lease agreement for its Tokyo office, effective October 2024, and in May 2024, the Company entered into a new lease agreement, effective June 2024, for a different office space for its Tokyo location. The new lease had an initial lease term of 12 months ending May 2025, following which the Company exercised its option to extend for an additional two months. Thereafter, there will be automatic two-month renewals until the lease is terminated. In measuring the lease liability, the Company determined that it was reasonably certain that it would exercise one renewal option. Accordingly, the Company used a lease term of 14 months in measuring the lease liability. The Company measured the lease liability based on the present value of the future lease payments, including the one extension option that is reasonably certain to be exercised, discounted using the estimated incremental borrowing rate of 6.51%, which is the interest rate that the Company would have to pay to borrow on a collateralized basis over a similar term for an amount equal to the lease payments at initial commencement. The real estate operating leases are included in "Right-of-use asset" on the Company's consolidated balance sheets and represents the Company's right to use the underlying assets for the lease term. The Company's obligation to make lease payments are included in "Operating lease liability" and "Other non-current liabilities" on the Company's consolidated balance sheets.

Information related to the Company's right-of-use assets and related lease liabilities are as follows:

	Year Ended December 31,	
	2025	2024
Cash paid for operating lease liabilities	$ 223,999	$ 261,069
Operating lease costs	204,236	258,647
Right-of-use assets obtained in exchange for new operating lease obligations	—	42,281
Current operating lease liabilities	$ 194,331	$ 193,769
Non-current operating lease liabilities	17,129	211,460
Total operating lease liabilities	$ 211,460	$ 405,229
Weighted-average remaining lease term	1.08	1.98
Weighted-average discount rate	9.8%	9.6%

Maturities of operating lease liabilities as of December 31, 2025 were as follows:

2026	$	206,483
2027		17,269
2028		—
2029		—
2030		—
Thereafter		—
Total minimum payments		223,752
Less imputed interest		(12,292)
Total lease liabilities	$	211,460

License and Research Agreements

The Company has entered into in-licensing agreements with various pharmaceutical companies. Under the terms of these agreements, the Company has received licenses to research, know-how and technology claimed in certain patents or patent applications. Under these license agreements, the Company is generally required to make upfront payments and additional payments upon the achievement of milestones and/or royalties on future sales of products until the later of the expiration of the applicable patent or the applicable last date of market exclusivity after the first commercial sale, on a country-by-country basis.

No milestone payments have been made under these agreements during the years ended December 31, 2025 and 2024. For products currently in development, future potential milestone payments based on product development of MN-166 (ibudilast) and MN-001 (tipelukast) are $10 million as of December 31, 2025. For all other products, future potential milestone payments related to development milestones and commercialization milestones totaled $16.5 million as of December 31, 2025. There are no minimum royalties required under any of the license agreements. The Company is unable to estimate with certainty the timing on when these milestone payments will occur as these payments are dependent upon the progress of the Company’s product development programs.

Legal Proceedings

From time to time, the Company may be subject to legal proceedings and claims in the ordinary course of business. The Company is not aware of any such proceedings or claims that it believes will have, individually or in aggregate, a material adverse effect on its business, financial condition or results of operations.

6. Stock-based Compensation

Stock Incentive Plans

In June 2013, the Company adopted the 2013 Equity Incentive Plan, or 2013 Plan, under which the Company granted equity-based awards, including stock options, stock appreciation rights, restricted stock, and restricted stock units to individuals who were then employees, officers, non-employee directors or consultants of the Company or its subsidiaries. A total of 8,700,000 shares of common stock were reserved for issuance under the 2013 Plan. In addition, “returning shares” that may become available from time to time were added back to the plan. “Returning shares” included shares that were subject to outstanding awards granted under the Company's prior 2004 Equity Incentive Plan that expired or terminated prior to exercise or settlement, were forfeited because of the failure to vest, were repurchased, or were withheld to satisfy tax withholding or purchase price obligations in connection with such awards. Although the Company no longer grants equity awards under the 2013 Plan, all outstanding stock awards granted under the 2013 Plan will continue to be subject to the terms and conditions as set forth in the agreements evidencing such stock awards and the terms of the 2013 Plan.

In June 2023, the Company adopted the 2023 Equity Incentive Plan, or 2023 Plan, under which the Company may grant stock options, stock appreciation rights, restricted stock, restricted stock units and other awards to individuals who are then employees, officers, non-employee directors or consultants of the Company or its subsidiaries. The 2023 Plan is the successor to the 2013 Plan. The number of shares of common stock that may be issued under the 2023 Plan is equal to the sum of (a) shares subject to awards granted under the 2013 Plan that were outstanding upon expiration of the 2013 Plan and are subsequently forfeited, expire or lapse unexercised or unsettled and shares issued pursuant to awards granted under the 2013 Plan that were outstanding upon expiration of the 2013

Plan and are subsequently forfeited to or reacquired by the Company and (b) shares reserved under the 2013 Plan that were not issued or subject to outstanding awards under the 2013 Plan upon expiration of the 2013 Plan. While a maximum of 9,934,567 shares may become available for issuance under the 2023 Plan from the 2013 Plan, since this figure assumes that all awards outstanding under the 2013 Plan upon expiration of the 2013 Plan will be forfeited, the Company expects the actual number of shares added to the 2023 Plan to be less. In general, to the extent that awards under the 2023 Plan are forfeited, cancelled or expire for any reason before being exercised or settled in full, the shares subject to such awards will again become available for issuance under the 2023 Plan. If stock appreciation rights are exercised or restricted stock units are settled, then only the number of shares (if any) actually issued to the participant will reduce the number of shares available under the 2023 Plan. If restricted shares or shares issued upon exercise of options are reacquired by the Company pursuant to a forfeiture provision, repurchase right or for any other reason, then such shares shall again become available for issuance under the 2023 Plan. Shares withheld to pay the exercise price of options or satisfy tax withholding obligations related to an award shall again become available for issuance under the 2023 Plan. Further, to the extent an award is settled in cash rather than shares, the cash settlement shall not reduce the number of shares available for issuance under the 2023 Plan.

As of December 31, 2025, 1,932,173 shares remain available for future grant under the 2023 Plan.

Certain of the employee stock options granted contain performance conditions, the vesting of which is based on a determination made by the board of directors or its compensation committee as to the achievement of certain corporate objectives at the end of the performance period. The grant date of such awards is the date on which the board of directors or its compensation committee makes its determination. For periods preceding the grant date, the expense related to these awards is measured based on their fair value at each reporting date. The estimated fair value of the performance awards granted and the resulting expense is based upon a certain level of achievement of the corporate objectives and other assumptions in determining fair value. The amount of expense ultimately recognized upon the grant date at completion of the performance period could change from the estimate as a result of various factors, including the level of achievement of the corporate objectives, changes in the assumptions used in the Black-Scholes model in determining fair value or fluctuations in the Company's stock price during the performance period. As of December 31, 2025, there were a total of 1,070,000 shares underlying performance options that were subject to vesting based on achievement of corporate objectives and employee performance for 2025. In January 2026, the compensation committee with the approval of the board of directors determined that the performance milestones were achieved at various levels, and accordingly 920,000 of these options vested and the remaining shares were forfeited.

Stock Options

Options granted under the 2023 Plan and the 2013 Plan have terms of ten years from the date of grant unless earlier terminated and generally vest over a one to four-year period.

The exercise price of all options granted during the years ended December 31, 2025 and 2024 was equal to the market value of the Company's common stock on the date of grant.

A summary of stock option activity and related information for the years ended December 31, 2025 and 2024 is as follows:

	Number of Option Shares	Weighted Average Exercise Price
Outstanding at December 31, 2023	7,781,749	$ 5.52
Granted	1,100,000	$ 1.51
Exercised	—	$ —
Forfeited	(430,105)	$ 1.98
Expired	(1,410,750)	$ 5.45
Outstanding at December 31, 2024	7,040,894	$ 5.12
Granted	1,480,500	$ 2.01
Exercised	—	$ —
Forfeited	(103,000)	$ 1.86
Expired	(416,000)	$ 3.08
Outstanding at December 31, 2025	8,002,394	$ 4.69
Exercisable at December 31, 2025	6,844,679	$ 5.14

	Number of Option Shares	Weighted Average Grant-Date Fair Value
Non-vested at December 31, 2024	860,000	$ 1.00
Granted	1,480,500	$ 1.34
Vested	(1,079,785)	$ 1.04
Forfeited	(103,000)	$ 1.23
Non-vested at December 31, 2025	1,157,715	$ 1.37

Options outstanding and exercisable at December 31, 2025 had a weighted average contractual life of 4.35 years and 4.05 years, respectively.

As of December 31, 2025 and 2024, the total intrinsic value of options outstanding was $3,000 and $0.5 million, respectively. Total intrinsic value of options exercisable was $1,500 and $25,840 as of December 31, 2025 and 2024, respectively. Total fair value of options vested was $1.1 million and $0.9 million for the years ended December 31, 2025 and 2024, respectively.

Compensation Expense

The Company uses the Black-Scholes valuation model for determining the estimated fair value for stock-based awards and considers management's current expectations of the achievement of the performance objectives for the year. The following table provides the weighted-average assumptions used in the Black-Scholes valuation model used to estimate the fair value of options granted during years ended December 31, 2025 and 2024, and to estimate the fair value of performance-based stock options as of December 31, 2025 and 2024:

	Year Ended December 31,	
	2025	2024
Stock Options		
Risk-free interest rate	3.89%	4.38%
Expected volatility of common stock	62.72%	72.25%
Dividend yield	0.00%	0.00%
Expected option term (in years)	4.69	4.62

The risk-free interest rate assumption is based upon observed interest rates appropriate for the expected term of employee stock options. The expected volatility is based on the historical volatility of the Company's common stock. The Company has not paid nor does the Company anticipate paying dividends on its common stock in the

foreseeable future. The expected term of employee stock options is based on the simplified method as provided by the authoritative guidance on stock compensation, as the historical stock option exercise experience does not provide a reasonable basis to estimate the expected term.

The weighted-average fair value of each stock option granted during the years ended December 31, 2025 and 2024, estimated as of the grant date using the Black-Scholes option valuation model, was $1.34 per option and $0.99 per option, respectively.

Stock-based compensation expense for stock option awards are reflected in total operating expenses for each respective year. The following table summarizes stock-based compensation expense for the years ended December 31, 2025 and 2024:

	December 31,	
	2025	2024
Research, development and patents	$ 304,852	$ 443,564
General and administrative	524,243	748,176
Total stock-based compensation expense	$ 829,095	$ 1,191,740

As of December 31, 2025, there was $0.1 million of unamortized compensation cost related to unvested stock option awards which is expected to be recognized over a remaining weighted-average vesting period of 0.05 years, on a straight-line basis.

7. Stockholders' Equity

At-The-Market Issuance Sales Agreement

On August 23, 2019, the Company entered into an at the market issuance sales agreement, which was amended on August 26, 2022 (as amended, the ATM Agreement) with B. Riley FBR, Inc. (B. Riley FBR) for the offer and sale of common stock through B. Riley FBR from time to time up to an aggregate offering price of $75.0 million.

No shares of common stock were sold under the ATM Agreement in the years ended December 31, 2025 and 2024, respectively.

On February 26, 2026 the Company notified B. Riley FBR that it was terminating the ATM agreement effective March 8, 2026.

Standby Equity Purchase Agreement

On July 30, 2025, the Company entered into a Standby Equity Purchase Agreement, or the SEPA with YA II PN, LTD., a Cayman Islands exempt limited company, or Yorkville. Pursuant to the SEPA, the Company has the right, but not the obligation, to sell to Yorkville from time to time up to $30.0 million of its common stock, during the 36 months following the execution of the SEPA, subject to the restrictions and satisfaction of the conditions in the SEPA. At the Company's option, the shares of common stock would be purchased by Yorkville from time to time at a price equal to 97% of the lowest of the three daily volume weighted average prices (VWAPs), during a three consecutive trading day period commencing on the date that the Company, subject to certain limitations, delivers to Yorkville a notice that the Company is committing Yorkville to purchase such shares of common stock. The Company may also specify a certain minimum acceptable price per share for a drawdown under the SEPA. As consideration for Yorkville's irrevocable commitment to purchase common stock, the Company paid Yorkville a $25,000 structuring fee along with a commitment fee of $375,000, recorded as General and Administrative expense. Under the applicable rules of Nasdaq and pursuant to the SEPA, in no event may the Company issue or sell to Yorkville more than 9,804,345 shares of common stock, or the Exchange Cap, which is 19.99% of the shares of common stock outstanding immediately prior to the execution of the SEPA, unless (i) the Company obtains stockholder approval to issue shares of common stock in excess of the Exchange Cap or (ii) the average price of all applicable shares of common stock under the SEPA equals or exceeds $1.33 per share (which represents the lower of (i) the Nasdaq Official Closing Price (as reflected on Nasdaq.com) on the trading day immediately preceding July 30, 2025 or (ii) the average Nasdaq Official Closing Price of the common stock (as reflected on Nasdaq.com) for the five trading days immediately preceding July 30, 2025). Pursuant to the SEPA, Yorkville shall not be obliged to

purchase or acquire any shares of common stock under the SEPA which, when aggregated with all other shares of the Company's common stock beneficially owned by Yorkville and its affiliates, would result in the beneficial ownership of Yorkville and its affiliates (on an aggregated basis) exceeding 4.99% of the then outstanding voting power or number of outstanding shares of the Company's common stock.

Pursuant to a financial advisory agreement between the Company and D. Boral Capital LLC (D. Boral), the Company has also agreed to pay D. Boral a fee equal to three percent of the gross proceeds received from any shares that the Company sells to Yorkville pursuant to the SEPA.

For the year ended December 31, 2025, the Company sold 175,000 shares of its common stock at prices ranging from $1.39 to $1.40 per share for proceeds of $0.2 million.

Equity Distribution Agreement

On December 29, 2025, the Company entered into an equity distribution agreement, with Lucid Capital Markets, LLC (Lucid) pursuant to which the Company may sell common stock through Lucid from time to time up to an aggregate offering price of $50.0 million (the Equity Distribution Agreement). Sales of the Company's common stock through Lucid, if any, will be made by any method that is deemed to be an "at-the-market" equity offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended, including sales made directly on Nasdaq, on any other existing trading market for the common stock or through a market maker. Lucid may also sell the common stock in privately negotiated transactions, subject to our prior approval. The Company agreed to pay Lucid an aggregate commission rate of 3.0% of the gross proceeds of any common stock sold under this agreement. Proceeds from sales of common stock will depend on the number of shares of common stock sold to Lucid and the per share purchase price of each transaction.

No shares of common stock were sold under the Equity Distribution Agreement in the year ended December 31, 2025.

Common Stock Reserved for Future Issuance

The following table summarizes common stock reserved for future issuance at December 31, 2025:

Common stock reserved for issuance upon exercise of options outstanding (under the 2004 Plan, 2013 Plan and 2023 Plan)	8,002,394
Common stock reserved for future equity awards (under the 2023 Plan)	1,932,173
	9,934,567

8. Income Taxes

A reconciliation of loss before income taxes for domestic and foreign locations for the years ended December 31, 2025 and 2024 is as follows:

	Year Ended December 31,	
	2025	2024
United States	$ (12,004,784)	$ (11,060,506)
Foreign	12,821	16,494
Loss before income taxes	$ (11,991,963)	$ (11,044,012)

A reconciliation of income tax expense for the years ended December 31, 2025 and 2024 is as follows:

	Year Ended December 31,	
Current:	2025	2024
Federal	$ —	$ —
State	—	—
Foreign	(5,994)	(5,537)
Total current income tax expense	(5,994)	(5,537)
Deferred:		
Federal	—	—
State	—	—
Foreign	—	—
Total deferred income tax expense	—	—
Total income tax expense	$ (5,994)	$ (5,537)

The significant components of deferred income taxes at December 31, 2025 and 2024 are as follows:

	Year Ended December 31,	
Deferred tax assets:	2025	2024
Net operating loss carryforwards	$ 67,509,750	$ 71,161,394
Research tax credits	8,564,654	9,173,787
Stock options	842,014	938,846
Other, net	264,626	269,439
Right-of-use liability	59,174	106,148
Research and experimentation capitalization	4,975,660	3,985,733
Total deferred tax assets	82,215,878	85,635,347
Deferred tax liabilities:		
Right-of-use asset	(51,554)	(94,000)
In-process research and development	(1,343,213)	(1,343,213)
Total deferred tax liabilities	(1,394,767)	(1,437,213)
Net deferred tax assets	80,821,111	84,198,134
Valuation allowance	(81,022,903)	(84,399,926)
Net deferred tax liability	$ (201,792)	$ (201,792)

The Company has established a valuation allowance against net deferred tax assets due to the uncertainty that such assets will be realized. The net change in the valuation allowance during the year ended December 31, 2025 was a decrease of $3.4 million. The Company periodically evaluates the recoverability of the deferred tax assets. At such time as it is determined that it is more likely than not that deferred tax assets will be realizable, the valuation allowance will be reduced.

	Year Ended December 31,	
	2025	2024
Valuation allowance - beginning of year	$ 84,399,926	$ 83,366,840
Allowance taken or written off	(3,375,117)	1,037,735
Other adjustment	(1,906)	(4,649)
Valuation allowance - end of year	$ 81,022,903	$ 84,399,926

At December 31, 2025, the Company has federal and California net operating loss (NOL) carryforwards of approximately $262.7 million and $194.3 million, respectively. $201.2 million of federal NOL carryforwards begin to expire in 2026, $61.5 million of federal NOL carryforwards can be carried forward indefinitely, and the California NOL carryforwards begin to expire in 2028. At December 31, 2025, the Company also had federal and

California research tax credit carry-forwards of approximately $7.5 million and $2.5 million, respectively. The federal research tax credit carryforwards begin to expire in 2026, and the California research tax credit carryforward does not expire and can be carried forward indefinitely until utilized.

The above NOL carryforward and the research tax credit carryforwards are subject to an annual limitation under Section 382 and 383 of the Internal Revenue Code of 1986, and similar state provisions due to ownership change limitations that have occurred which will limit the amount of NOL and tax credit carryforwards that can be utilized to offset future taxable income and tax, respectively. In general, an ownership change, as defined by Section 382 and 383, results from transactions increasing ownership of certain stockholders or public groups in the stock of the corporation by more than 50 percentage points over a three-year period. The Company completed an IRC Section 382/383 analysis regarding the limitation of net operating loss and research and development credit carryforwards for a period of inception through December 2023, and did not experience any ownership changes which triggers the limitation. There is a risk that additional changes in ownership have occurred since the completion of the Company's analysis. If a change in ownership were to have occurred, additional NOL and tax credit carryforwards could be eliminated or restricted. If eliminated, the related asset would be removed from the deferred tax asset schedule with a corresponding reduction in the valuation allowance. Due to the existence of the valuation allowance, limitations created by future ownership changes, if any, related to the Company's operations in the United States will not impact the Company's effective tax rate.

On July 5, 2025, the reconciliation bill, commonly referred to as the One Big Beautiful Bill Act (OBBBA), was signed into law in the United States, which includes a broad range of tax reform provisions. Beginning in 2025, the OBBBA provides an elective deduction for domestic research and development expenses, a reinstatement of elective 100% first-year bonus depreciation and repeal of non-United States corporations' fiscal year end. Some impacts of the OBBBA will not be realized until 2026 and forward, such as a more favorable tax rate on Foreign-Derived Deduction Eligible Income and income from non-United States subsidiaries (Net CFC Tested Income). Due to the nature of the tax law changes, the Company has not realized an impact in the Statement of Operations related to deferred taxes. The Company will continue to monitor the impact of the OBBBA and the range of potential outcomes.

The income taxes paid by the Company are as follows:

	Year Ended December 31,	
	2025	2024
Federal	$ —	$ —
Disaggregated state and local jurisdictions		
California	—	—
Foreign		
Japan	5,994	5,042
Net cash paid for income taxes	$ 5,994	$ 5,042

A reconciliation of the federal statutory income tax rate to the Company's effective income tax rate is as follows:

	Year Ended December 31,			
	2025		2024	
	$	%	$	%
U.S. federal statutory rate	$ (2,518,312)	21.0%	$ (2,319,243)	21.0%
State income taxes, net of federal benefit	—	—	(177,062)	1.6
Foreign tax effects				
Japan				
Statutory tax rate difference between Japan and U.S.	1,228	—	(113)	—
Prior year liability true-up	2,295	—	1,913	—
Tax Credits				
Research and development credits	(169,175)	1.4	(438,062)	4.0
Changes in valuation allowance	(3,637,650)	30.3	622,084	(5.6)
Nontaxable or nondeductible items				
Stock-based payment awards	20,242	(0.2)	73,312	(0.7)
Other permanent items	91,336	(0.7)	3,856	—
Changes in unrecognized tax benefits	(71,782)	0.6	988,657	(8.9)
Other adjustments				
Expiration of tax attributes - net operating loss	5,175,472	(43.1)	325,535	(3.0)
Expiration of tax attributes - research and credits	887,000	(7.4)	327,127	(3.0)
Stock option cancellation	200,020	(1.7)	739,817	(6.7)
IRC Sec. 162(m) deferred tax asset limit	25,323	(0.2)	(143,665)	1.3
Return-to-provision true-up and others	(3)	—	1,381	—
Provision for income taxes	$ 5,994	0.0%	$ 5,537	0.0%

The Company determines its uncertain tax positions based on a determination of whether and how much of a tax benefit taken by the Company in its tax filings is more likely than not to be sustained upon examination by the relevant income tax authorities.

The following table summarizes the activity related to the Company's unrecognized tax benefits:

	Year Ended December 31,	
	2025	2024
Gross unrecognized tax benefits at January 1	$ 2,697,076	$ 1,589,266
Additions for tax positions taken in the prior year	—	1,079,358
Decrease for tax positions taken in the prior year	(36,511)	—
Expired for tax positions taken in the prior year	(88,700)	—
Additions for tax positions taken in the current year	22,109	28,452
Gross unrecognized tax benefits at December 31	$ 2,593,974	$ 2,697,076

If recognized, none of the unrecognized tax benefits as of December 31, 2025 would reduce the annual effective tax rate, primarily due to corresponding adjustments to the valuation allowance.

The Company files income tax returns in the United States, California and foreign jurisdictions. Due to the Company's losses incurred, the Company is subject to income tax examination by tax authorities from inception to date. At December 31, 2025, there are no significant accruals for interest related to unrecognized tax benefits or tax penalties. The Company does not expect the unrecognized tax benefits to change significantly over the next twelve months.

9. Employee Savings Plan

The Company has an employee savings plan available to substantially all employees. Under the plan, an employee may elect salary reductions which are contributed to the plan. The plan provides for discretionary contributions by the Company, which totaled $70,004 and $84,826 for the years ended December 31, 2025 and 2024, respectively.

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

An evaluation was performed by our Chief Executive Officer and Chief Financial Officer of the effectiveness of the design and operation of our disclosure controls and procedures as defined in the Rules 13(a)-15(e) of the Securities Exchange Act of 1934, as amended (the Exchange Act). Disclosure controls and procedures are those controls and procedures designed to provide reasonable assurance that the information required to be disclosed in our Exchange Act filings is (1) recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission's rules and forms, and (2) accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2025, our disclosure controls and procedures were effective.

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our procedures or our internal controls will prevent or detect all errors and all fraud. An internal control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of the inherent limitations in all control systems, no evaluation of our controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected.

Changes in Internal Control over Financial Reporting

There was no change in internal control over financial reporting (as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) during our fourth fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Management's Report on Internal Control over Financial Reporting

Internal control over financial reporting refers to the process designed by, or under the supervision of, our Chief Executive Officer and Chief Financial Officer, and effected by our board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles, and includes those policies and procedures that:

(1) Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;

(2) Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorization of our management and directors; and

(3) Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Internal control over financial reporting cannot provide absolute assurance of achieving financial reporting objectives because of its inherent limitations. Internal control over financial reporting is a process that involves human diligence and compliance and is subject to lapses in judgment and breakdowns resulting from human

failures. Internal control over financial reporting also can be circumvented by collusion or improper management override. Because of such limitations, there is a risk that material misstatements may not be prevented or detected on a timely basis by internal control over financial reporting. However, these inherent limitations are known features of the financial reporting process. Therefore, it is possible to design into the process safeguards to reduce, though not eliminate, this risk. Management is responsible for establishing and maintaining adequate internal control over financial reporting for the company.

Management has used the framework set forth in the report entitled Internal Control-Integrated Framework (2013 framework) published by the Committee of Sponsoring Organizations of the Treadway Commission, known as COSO, to evaluate the effectiveness of our internal control over financial reporting. Based on this assessment, management has concluded that our internal control over financial reporting was effective as of December 31, 2025.

Item 9B. Other Information

Securities Trading Plans of Directors and Executive Officers

During the last fiscal quarter of the year ended December 31, 2025, none of our officers or directors, as defined in Rule 16a-1(f), informed us of the adoption or termination of a Rule 10b5-1 trading arrangement or a non-Rule 10b5-1 trading arrangement, each as defined in Regulation S-K Item 408.

Item 9C. Disclosure Regarding Foreign Jurisdiction the Prevent Inspections

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this item and not set forth below will be contained in our definitive proxy statement in connection with our 2026 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the conclusion of our fiscal year ended December 31, 2025 (Proxy Statement) and is incorporated in this Annual Report on Form 10-K by reference.

We have adopted a Code of Ethics for Senior Officers (Code of Ethics), that applies to our Chief Executive Officer, President, Chief Financial Officer and key management employees (including other senior financial officers) who have been identified by our board of directors. We have also adopted a Code of Business Conduct that applies to all of our officers, directors, employees, consultants and representatives. Each of the Code of Ethics and Code of Business Conduct are available on our website at *www.medicinova.com* under the Corporate Governance section of our Investor Relations page. We will promptly post on our website (i) any waiver, if and when granted, to any provision of the Code of Ethics or Code of Business Conduct (for executive officers or directors) and (ii) any amendment to the Code of Ethics or Code of Business Conduct.

We have adopted an insider trading policy governing the purchase, sale and other dispositions of our securities by our directors, officers and employees that we believe is reasonably designed to promote compliance with insider trading laws, rules and regulations, and any applicable listing standards. A copy of our insider trading policy is filed as Exhibit 19.1 to this Annual Report on Form 10-K.

Item 11. Executive Compensation

The information required by this item will be contained in our Proxy Statement and is incorporated in this Annual Report on Form 10-K by reference.

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

Certain of the information required by this item will be contained in our Proxy Statement and is incorporated in this Annual Report on Form 10-K by reference.

The following table provides information as of December 31, 2025 with respect to the shares of our common stock that may be issued under our existing equity compensation plans.

Equity Compensation Plan Information

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options and Rights	Weighted Average Exercise Price of Outstanding Options and Rights	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans
Equity Compensation Plans Approved by Stockholders (1)	8,002,394	$ 4.69	1,932,173
Equity Compensation Plans not approved by security holders	—	—	—
Total	8,002,394	$ 4.69	1,932,173

(1) Consists of the Amended and Restated 2004 Stock Incentive Plan, the 2013 Equity Incentive Plan, the 2023 Equity Incentive Plan, and the 2007 Employee Stock Purchase Plan (ESPP).

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

The information required by this item will be contained in our Proxy Statement and is incorporated in this Annual Report on Form 10-K by reference.

Item 14. Principal Accountant Fees and Services

The information required by this item will be contained in our Proxy Statement and is incorporated in this Annual Report on Form 10-K by reference.

PART IV

Item 15. Exhibits and Financial Statement Schedules

(a) *Documents filed as part of this report.*

1. *Financial Statements.* The following financial statements of MediciNova, Inc. and report of BDO USA, P.C, an independent registered public accounting firm, are included in this Annual Report on Form 10-K (included in Part II of this Annual Report on Form 10-K):

2. *Financial Statement Schedules.* None.

3. *Exhibits.*

Exhibit Number	Description
3.1	Restated Certificate of Incorporation of the Registrant, as amended (incorporated by reference to Exhibit 3.1 of the Registrant's Quarterly Report on Form 10-Q (File No. 001-33185) filed August 9, 2012).
3.2	Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.4 of the Registrant's Registration Statement on Form S-1 (File No. 333-119433) filed October 1, 2004).
4.1	Specimen of Common Stock Certificate (incorporated by reference to Exhibit 4.1 of the Registrant's Annual Report on Form 10-K (File No. 001-33185) filed February 15, 2007).
4.2	Amended and Restated Registration Rights Agreement, dated September 2, 2004, among the Registrant, its founders and the investors named therein (incorporated by reference to Exhibit 4.2 of the Registrant's Registration Statement on Form S-1 (File No. 333-119433) filed October 1, 2004).
4.3	Description of Capital Stock (incorporated by reference to Exhibit 4.3 of the Registrant's Annual Report on Form 10-K (File No. 001-33185) filed February 19, 2021).
10.1*	Form of Indemnity Agreement between the Registrant and its officers and directors (incorporated by reference to Exhibit 10.3 of the Registrant's Annual Report on Form 10-K (File No. 001-33185) filed March 28, 2013).
10.2*	2007 Employee Stock Purchase Plan of the Registrant (incorporated by reference to Appendix A of the Registrant's Definitive Proxy Statement on Schedule 14A (File No. 001-33185) filed March 13, 2007).
10.3*	2013 Equity Incentive Plan of the Registrant (incorporated by reference to Exhibit 10.23 of the Registrant's Annual Report on Form 10-K (File No. 001-33185) filed March 27, 2014).
10.4*	Amended and Restated 2013 Equity Incentive Plan of the Registrant. (incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q (File No. 001-33185) filed July 26, 2017).
10.5*	Form of Notice of Stock Option Grant and Stock Option Agreement for awards pursuant to the 2013 Equity Incentive Plan (incorporated by reference to Exhibit 10.3 of the Registrant's Quarterly Report on Form 10-Q (File No. 001-33185) filed November 7, 2013).
10.6*	2023 Equity Incentive Plan and forms of award agreements thereunder of the Registrant (incorporated by reference to Exhibit 99.1 of the Registrant's Post-Effective Amendment No. 1 to Registration Statements on Form S-8 (File Nos. 333-264938, 333-232239, 333-219491, 333-190490) filed January 19, 2024).

Exhibit Number	Description
10.7*	Executive Employment Agreement, dated April 1, 2007, between the Registrant and Yuichi Iwaki, M.D., Ph.D. (incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K (File No. 001-33185) filed April 4, 2007).
10.8*	Form of First Amendment to Employment Agreement, dated December 31, 2010, between the Registrant and Yuichi Iwaki, M.D., Ph.D. (incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K (File No. 001-33185) filed January 4, 2011).
10.9*	Severance Protection Agreement, dated July 14, 2014, between the Registrant and Dr. Yuichi Iwaki (incorporated by reference to Exhibit 10.2 of the Registrant's Quarterly Report on Form 10-Q (File No. 001-33185) filed August 13, 2014).
10.10*	Severance Protection Agreement, dated July 14, 2014, between the Registrant and Dr. Kazuko Matsuda (incorporated by reference to Exhibit 10.4 of the Registrant's Quarterly Report on Form 10-Q (File No. 001-33185) filed August 13, 2014).
10.11*	Severance Protection Agreement, dated July 14, 2014, between the Registrant and Geoffrey O'Brien (incorporated by reference to Exhibit 10.5 of the Registrant's Quarterly Report on Form 10-Q (File No. 001-33185) filed August 13, 2014).
10.12*	Consulting Agreement, dated April 2, 2024, between the Registrant and Geoffrey O'Brien (incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q (File No. 001-33185) filed August 8, 2024).
10.13	Lease, dated July 20, 2021, between MediciNova, Inc. and the Irvine Company LLC (incorporated by reference to Exhibit 99.1 of the Registrant's Current Report on Form 8-K (File No. 001-33185) filed July 23, 2021).
10.14†	Assignment Agreement, dated December 19, 2005, between Genzyme Corporation and Avigen, Inc. (incorporated by reference to Exhibit 10.58 of Avigen, Inc.'s Annual Report on Form 10-K (File No. 000-28272) filed March 16, 2006).
10.15	Securities Purchase Agreement, dated January 11, 2021, between the Company and 3D Opportunity Master Fund (incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K (File No. 001-33185) filed January 12, 2021).
10.16	Shareholder Rights Agreement, dated January 11, 2021, between the Company and 3D Opportunity Master Fund (incorporated by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K (File No. 001-33185) filed January 12, 2021).
10.17	Services Agreement, dated August 1, 2021, between MediciNova, Inc. and Signature Analytics LLC (acquired by Citrin Cooperman Advisors LLC) (incorporated by reference to Exhibit 99.1 of the Registrant's Current Report on Form 8-K (File No. 001-33185) filed August 2, 2021).
10.18	Standby Equity Purchase Agreement dated as of July 30, 2025 by and between the Company and YA II PN Ltd. (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-33185) filed August 1, 2025).
10.19	Equity Distribution Agreement by and between the Company and Lucid Capital Markets, LLC, dated December 29, 2025 (incorporated by reference to Exhibit 1.1 to the Registrant's Current Report on Form 8-K (File No. 001-33185) filed December 30, 2025).
19.1	MediciNova, Inc. Statement of Company Policy, Trades in the Company's Securities by Insiders and Confidential Information.
21	Subsidiaries of the Registrant (incorporated by reference to Exhibit 21 of the Registrant's Annual Report on Form 10-K/A (File No. 001-33185) filed March 28, 2023).
23.1	Consent of Independent Registered Public Accounting Firm.
24.1	Powers of Attorney (see signature page).
31.1	Certification of the Principal Executive Officer pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Act of 1933.
31.2	Certification of the Principal Financial Officer pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Act of 1933.

Exhibit Number	Description
32.1	Certification of the Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of the 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	MediciNova, Inc. Recovery of Erroneously Awarded Compensation Policy (incorporated by reference to Exhibit 97.1 of the Registrant's Annual Report on 10-K (File No. 001-33185) filed February 15, 2024).
101	The following financial statements from MediciNova, Inc. on Form 10-K as of and for the year ended December 31, 2025 formatted in Extensible Business Reporting Language (XBRL): (i) Consolidated Balance Sheets; (ii) Consolidated Statements of Operations and Comprehensive Loss; (iii) Consolidated Statements of Stockholders' Equity; (iv) Consolidated Statements of Cash Flows; and (v) the notes to the consolidated financial statements.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

† Portions of this Exhibit have been omitted pursuant to a grant of confidential treatment by the SEC.
* Indicates management contract or compensatory plan.

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 Annual Report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized.

MEDICINOVA, INC.
A Delaware Corporation

Date: March 10, 2026

By: /s/ Yuichi Iwaki
Yuichi Iwaki, M.D., Ph.D.
President & Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Yuichi Iwaki his or her true and lawful attorney-in-fact, with full power of substitution, for him or her in any and all capacities, to sign any amendments to this Annual Report on Form 10-K and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that said attorney-in-fact or his or her substitute or substitutes may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this Annual Report on Form 10-K has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Yuichi Iwaki Yuichi Iwaki, M.D., Ph.D.	Chairman of the Board of Directors, President and Chief Executive Officer *(Principal executive officer)*	March 10, 2026
/s/ Jason Kruger Jason Kruger	Chief Financial Officer *(Principal financial and accounting officer)*	March 10, 2026
/s/ Carolyn Beaver Carolyn Beaver	Director	March 10, 2026
/s/ Nicole Lemerond Nicole Lemerond	Director	March 10, 2026
/s/ Kazuko Matsuda Kazuko Matsuda	Director	March 10, 2026
/s/ Hideki Nagao Hideki Nagao	Director	March 10, 2026


MEDICINOVA