REFINITIV

DELTA REPORT

10-K

MNOV - MEDICINOVA INC

10-K - DECEMBER 31, 2023 COMPARED TO 10-K - DECEMBER 31, 2022

The following comparison report has been automatically generated

TOTAL DELTAS	1856
CHANGES	264
DELETIONS	473
ADDITIONS	1119

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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, 2022 2023

or

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

For the transition period from. to

Commission file number: 001-33185

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 Nasdaq Stock Market LLC

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

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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 an 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 Securities Exchange Act of 1934). Yes ☐ No ☒

The aggregate market value of the registrant’s common stock held by non-affiliates of the registrant was approximately $117,554,962 109,440,898 based on the closing price of the registrant’s common stock on the NASDAQ Global Market of $2.53 $2.30 per share on June 30, 2022 June 30, 2023. 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 February 13, 2023 February 12, 2024 was 49,046,246.

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 2023 2024 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, 2022 December 31, 2023

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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 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 th underlying licensing agreement;
- Competitors may develop products rendering our product candidates obsolete and noncompetitive;
- The widespread outbreak of an illness or any other communicable disease, such as COVID-19, which has led t key employees becoming ill for a period of time;
- 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 pa 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;
- 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 this 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 uncertaint 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, NAFLD, and IPF 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 mor 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 the ongoing COVID-19 pandemic or any other illness or communicable disease, or any other public hea crisis on our business;

- 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 cybe attacks;
- 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;

- 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 Nasdaq Global Market or the Standard Market of the Tok 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 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, substance dependence and addiction (e.g., methamphetamine dependence, opioid dependence, and alcohol dependence), and prevention of acute respiratory distress syndrome (ARDS), and Long COVID, and MN-001 (tipelukast) for fibrotic and other diseases such as nonalcoholic fatty liver disease (NAFLD) and idiopathic pulmonary fibrosis (IPF). Our pipeline also includes MN-221 (bedoradrine) for the treatment of acute exacerbation of asthma and MN-029 (denibulin) for solid tumor cancers. MN-166 (ibudilast) is in development for several different neurological diseases and other diseases as described below.

Progressive Multiple Sclerosis:

We completed a Phase 2b clinical trial of MN-166 (ibudilast) for the treatment of relapsing multiple sclerosis (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 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 = ratio=0.74), as measured by EDSS (Expanded Disability Status Scale). 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 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 United States Food and Drug Administration (FDA) has granted Fast Track designation for the development of MN-166 (ibudilast) for the treatment of patients with progressive MS.

Amyotrophic Lateral Sclerosis (ALS):

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 U.S. Patent and Trademark Office 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. 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 (amyotrophic lateral sclerosis/motor neurone disease) 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.

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.

Substance Dependence and Addiction:

In the area of addiction, the National Institute on Drug Abuse (NIDA) funded a Phase 2 clinical trial of MN-166 (ibudilast) for the treatment of methamphetamine addiction. In collaboration with the University of California, Los Angeles (UCLA), this clinical trial commenced in 2013 and enrollment was completed in September 2017. In March 2018, we announced that this trial did not meet the primary endpoint of methamphetamine abstinence confirmed via urine drug screens during the final two weeks of treatment. In November 2017, we announced a collaboration with Oregon Health & Science University to initiate a biomarker study for evaluating MN-166 (ibudilast) in methamphetamine use disorder and this trial is ongoing.

Investigators at Columbia University and the New York State Psychiatric Institute (NYSPI) previously completed a Phase 1b/2a clinical trial of MN-166 (ibudilast) in opioid withdrawal that was funded by NIDA. Investigators at Columbia University and the NYSPI also conducted a NIDA-funded, Phase 2a clinical trial to evaluate the efficacy of MN-166 (ibudilast) in the treatment of patients addicted to prescription opioids or heroin. In March 2016, we announced that positive findings from the results of this completed study in opioid dependence were presented at the Behavior, Biology and Chemistry: Translational Research in Addiction Meeting.

Researchers at UCLA were granted approval and funding by the National Institute on Alcoholism and Alcohol Abuse (NIAAA) for a clinical trial to evaluate MN-166 (ibudilast) for the treatment of alcohol dependence. This clinical trial has been completed and results were presented at the American College of Neuropsychopharmacology (ACNP)'s 54th Annual Meeting in December 2015. In May 2018, we announced a new NIDA-funded clinical trial of MN-166 (ibudilast) in alcohol dependence and withdrawal in collaboration with researchers at UCLA. This clinical trial has been completed and positive findings were presented at the American Psychological Association 2020 Annual Convention which was held online in August 2020. Results from this clinical trial were published in June 2021 in Nature's *Translational Psychiatry.* In August 2018, we announced a new NIAAA-funded Phase 2b clinical trial of MN-166 (ibudilast) which will to evaluate heavy drinking days in subjects with alcohol dependence in collaboration with researchers at UCLA and this trial is ongoing. has been completed. In February 2022, we announced that MN-166 (ibudilast) was discussed as one of the promising pharmacological agents for the treatment of alcohol use disorder in the journal *Drugs*. In April 2022, we announced that a secondary analysis of a Phase 2 clinical trial of MN-166 (ibudilast) in alcohol use disorder was published in the journal *Alcoholism: Clinical and Experimental Research*. In December 2022, we announced that positive results from a secondary analysis of a Phase 2 trial of MN-166 (ibudilast) in alcohol use disorder were published in *The American Journal of Drug and Alcohol Abuse*. In January 2023, we announced that the Phase 2b clinical trial of MN-166 (ibudilast) for the treatment of alcohol use disorder had completed enrollment. In June 2023, we announced results of the Phase 2b clinical trial of MN-166 (ibudilast) in alcohol use disorder which were presented at the 46th Annual Research Society on Alcoholism (RSA) Scientific Meeting.

Chemotherapy-Induced Peripheral Neuropathy: In March 2018, we announced plans to initiate a clinical trial to evaluate MN-166 (ibudilast) as a treatment for prevention of chemotherapy-induced peripheral neuropathy (CIPN) which was funded by the University of Sydney Concord Cancer Centre in Australia. In September 2020, we announced that positive clinical findings from this clinical trial were published in *Cancer Chemotherapy and Pharmacology*. In October 2020, we announced plans to initiate a multi-center, placebo-controlled, randomized Phase 2b trial to evaluate MN-166 (ibudilast) in CIPN, which is funded by the Australasian Gastro-Intestinal Trials Group (AGITG), and this trial is ongoing.

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 and this trial is ongoing. 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 has 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 (Society for Brain Mapping and Therapeutics). 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.

Prevention of Acute Respiratory Distress Syndrome ARDS in patients with COVID-19: In March 2020, we announced plans to initiate development of MN-166 (ibudilast) for severe pneumonia and acute respiratory distress syndrome (ARDS) 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 August 2021, we announced completion of 75% of planned enrollment in this Phase 2 clinical trial. 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

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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.

Chlorine Gas-Induced Lung Injury: In March 2021, we announced a partnership with the Biomedical Advanced Research and Development Authority (BARDA), part of the Office of the Assistant Secretary Administration for Strategic Preparedness and Response at (ASPR) in the U.S. Department of Health and Human Services, to develop MN-166 (ibudilast) as a potential medical countermeasure (MCM) against chlorine gas-induced lung damage such as acute respiratory distress syndrome (ARDS) ARDS and acute lung injury (ALI). BARDA agreed to provide federal funding for proof-of-concept studies of MN-166 (ibudilast) in preclinical models of chlorine gas-induced acute lung injury under Contract No. 75A50121C00022. In June 2021, September 2023, we announced initiation the results of a sheep study to investigate MN-166 (ibudilast) in an ovine model of chlorine-induced acute lung injury and this study is ongoing. In June 2021, we also announced a mouse study to investigate the efficacy of MN-166 (ibudilast) in a murine model of chlorine-induced lung injury and lethality. In June 2022, we announced a modification to studies conducted under our contract with BARDA BARDA. The primary endpoint of the first nonclinical efficacy study was the pulmonary function measure PaO2/FiO2, which is the ratio of arterial oxygen partial pressure to fractional inspired oxygen. In the pilot design single-dose treatment regimen, MN-166 (ibudilast) high dose and the positive control rolipram were more efficacious than MN-166 (ibudilast) low dose and the negative control until 12 hours after chlorine exposure but this did not yield statistically significant results for overall pulmonary function. In the multi-dose study, each treatment was given every 12 hours with a total of four doses after the chlorine gas challenge. Treatment with MN-166 (ibudilast) high dose resulted in which greater improvement (p=0.0001) in the contract mean PaO2/FiO2 ratio than MN-166 (ibudilast) low dose, rolipram, and the negative control. MN-166 (ibudilast)

was amended well tolerated and no safety concerns were observed in the first nonclinical efficacy study. After multiple attempts by our subcontractor to extend establish the period feasibility of performance until March 2023. the second chlorine-gas induced lung injury model, it was not deemed to be a feasible model to evaluate a drug candidate and there are no evaluable efficacy results.

Long COVID: In August 2022, we announced plans to participate in RECLAIM (Recovering from COVID-19 Lingering Symptoms Adaptive Integrative Medicine Trial), a grant-funded, multi-center, randomized, clinical trial to evaluate MN-166 (ibudilast) and other therapies for the treatment of Long COVID, the lingering symptoms of COVID-19. In February 2023, we announced that Health Canada completed its review of the clinical trial application and granted authorization to commence the RECLAIM trial. trial and this study is ongoing.

MN-001 (tipelukast) is in development for fibrotic and other diseases 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.

Idiopathic Pulmonary Fibrosis (IPF): In 2014, we announced positive results of MN-001 (tipelukast) in a mouse model of pulmonary fibrosis. The FDA subsequently granted Orphan-Drug designation to MN-001 (tipelukast) for treatment of IPF which will provide seven years of marketing exclusivity if MN-001 (tipelukast)

is approved for IPF. The FDA granted Fast Track designation to MN-001 (tipelukast) for the treatment of patients with IPF in September 2015. We then initiated a Phase 2 clinical trial of MN-001 (tipelukast) to treat IPF and we announced results of this trial in August 2021. Although there were no clinically meaningful trends in favor of MN-001 (tipelukast) for the majority of the clinical outcome measures in this small study, there were no worsening IPF events (acute IPF exacerbation or hospitalization due to respiratory symptoms) in the MN-001 (tipelukast) group compared to one worsening IPF event in the placebo group. MN-001 (tipelukast) demonstrated a substantial reduction in LOXL2, a biomarker for IPF, whereas LOXL2 increased in the placebo group. MN-001 (tipelukast) was safe and well tolerated.

We completed a Phase 2 clinical trial of MN-221 (bedoradrine) for the treatment of acute exacerbations of asthma treated in the emergency room and conducted an End-of-Phase 2 meeting with the FDA in October 2012. In that meeting, the FDA identified the risk/benefit profile of MN-221 (bedoradrine) as a focal point for further development and advised that a clinical outcome, such as a reduction in hospitalizations, would need to be a primary endpoint in a pivotal trial. We believe the appropriate clinical development for MN-221 (bedoradrine) would involve conducting dose regimen and acute exacerbations of asthma trial design optimization studies prior to commencing pivotal trials. We are working plan to identify a partner for financial support before further clinical development is commenced.

We acquired licenses to MN-166 (ibudilast), MN-001 (tipelukast), MN-221 (bedoradrine), and MN-029 (denibulin) for the development of these product candidates. The MN-221 (bedoradrine) license agreement was terminated in October 2022. We have pursued development of these product candidates in various indications including COVID-19, prevention of acute respiratory distress syndrome, Long COVID, progressive MS, ALS, chemotherapy-induced peripheral neuropathy, degenerative cervical myelopathy, glioblastoma, various addictions, NASH and NAFLD, IPF, acute exacerbations of asthma, and solid tumor cancers.

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 diseases.*

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), MN-001 (tipelukast), MN-221 (bedoradrine), and MN-029 (denibulin), 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 20 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, chemotherapy-induced peripheral neuropathy, degenerative cervical myelopathy, glioblastoma, substance dependence, and prevention of acute respiratory distress syndrome. syndrome, and Long COVID. We licensed MN-166 (ibudilast) from Kyorin Pharmaceuticals (Kyorin) in 2004.

The FDA has granted Fast Track designations to MN-166 (ibudilast) for three separate indications: the treatment of progressive MS, the treatment of ALS, and the treatment of methamphetamine dependence. 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, for the treatment of glioblastoma, for the treatment of drug addiction or dependence, and for the treatment of neuropathic pain.

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, or NMSS. Also, according to NMSS, approximately 85 percent of people with MS are initially diagnosed with relapsing-remitting MS, or RRMS, and

some people who are initially diagnosed with RRMS will eventually transition to secondary progressive MS, or SPMS. About 15 percent of people with MS are diagnosed with primary progressive MS, or 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 = ratio=0.74), as measured by EDSS (Expanded Disability Status Scale).

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, pRNFL (peripapillary retinal nerve fiber layer) 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 U.S. Patent and Trademark Office for a new patent which covers MN-166 (ibudilast) for the treatment of an ophthalmic

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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): 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 three 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 American Academy of Neurology (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 (amyotrophic lateral sclerosis/motor neurone disease) 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 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 United States Patent and Trademark Office (PTO) 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 U.S. PTO 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 (amyotrophic lateral sclerosis/motor neurone disease) 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.

Methamphetamine Addiction: Methamphetamine is a central nervous system stimulant drug that is similar in structure to amphetamine. It is a Schedule II drug, meaning that it has high abuse potential and low therapeutic potential. According to the Substance Abuse and Mental Health Services Administration's (SAMHSA) 2021 2022 National Survey on Drug Use and Health, there are approximately 1.6 million 1.8 million people aged 12 or older with methamphetamine use disorder in the United States. The Rand Corporation has estimated that the economic burden of methamphetamine use in the United States is approximately $23.4 billion. Currently, there is no pharmaceutical treatment approved for methamphetamine dependence. Based on non-clinical results of the effects of MN-166 (ibudilast) in an animal model of methamphetamine relapse, investigators at UCLA conducted a Phase 1b clinical trial funded by NIDA to examine the safety and preliminary efficacy of MN-166 (ibudilast) in non-treatment-seeking, methamphetamine-dependent users in an inpatient trial that was completed in 2012. Subsequently, UCLA investigators received NIDA grant funding for a Phase 2 clinical trial to evaluate MN-166 (ibudilast) in methamphetamine-dependent users in an outpatient trial setting that commenced in 2013. In March 2018, we announced that this trial did not meet the primary endpoint of methamphetamine abstinence confirmed via urine drug screens during the final two weeks of treatment. In November 2017, we announced a collaboration with Oregon Health & Science University to initiate a biomarker study to evaluate MN-166 (ibudilast) in methamphetamine use disorder and this study is ongoing. We were granted Fast Track designation from the FDA for MN-166 (ibudilast) for the treatment of methamphetamine dependence in 2013.

Opioid Withdrawal and Dependency: According to the SAMHSA's 2021 2022 National Survey on Drug Use and Health, there are approximately 5.0 million 5.6 million people aged 12 or older with prescription pain reliever use disorder and approximately 1.0 million 0.9 million people aged 12 or older with heroin use disorder in the United States. Access to prescription opioids has recently become more difficult due to more stringent policies on prescribing opioids. An unintended consequence of this policy is increased use of heroin. Heroin is attractive to prescription opioid addicts because it is less expensive and more accessible than prescription opioids. Heroin poses serious health issues, such as risk of HIV and Hepatitis C infection, overdose, and death. There is an urgent, significant unmet medical need for a safe, effective non-addictive, non-opioid therapy for the treatment of prescription opioid and heroin addiction. Investigators at Columbia University and NYSPI previously completed a NIDA-funded, randomized, double-blind, placebo-controlled in-unit Phase 1b/2a clinical trial to evaluate the ability of MN-166 (ibudilast) to reduce opioid withdrawal symptoms in humans. Subsequently, investigators at Columbia University and NYSPI conducted a NIDA-funded Phase 2a clinical trial of MN-166 (ibudilast) for the treatment of prescription opioid or heroin dependence. In March 2016, we announced that positive findings from the results of this completed study in opioid dependence were presented at the Behavior, Biology and Chemistry: Translational Research in Addiction Meeting.

Alcohol Addiction: According to SAMHSA's 2021 2022 National Survey on Drug Use and Health, there are approximately 29.5 million people aged 12 or older in the United States with alcohol use disorder. The Centers for Disease

Control and Prevention (CDC) has reported that excessive alcohol use costs the United States $249 billion

per year. Medicines that have been approved by the FDA to treat alcohol dependence include Antabuse® (disulfiram), Vivitrol® (naltrexone), Campral® (acamprosate) and Revia® (naltrexone). However, the search for a safe and effective drug remains elusive due to limited success of these FDA-approved compounds (Witkiewitz *et al*., 2012). In a non-clinical trial (Bell *et al*., 2013), MN-166 (ibudilast) was examined in rats and mice and was found to reduce alcohol drinking in alcohol-preferring P rats and high-alcohol drinking (HAD1) rats by 50%, and in mice made dependent on alcohol at doses which had no effect on non-dependent mice. Investigators at UCLA received funding from the NIAAA to conduct a study to evaluate MN-166 (ibudilast) with a randomized, double-blind, placebo-controlled within-subject crossover design to determine the safety, tolerability and initial human laboratory efficacy of MN-166 (ibudilast) in a sample of 24 non-treatment seeking individuals with either alcohol abuse or dependence. Results of the alcohol dependence study were presented at the American College of Neuropsychopharmacology (ACNP)'s 54th Annual Meeting in December 2015. MN-166 (ibudilast), but not placebo, significantly decreased basal, daily alcohol craving over the course of

the study ($p<0.05$). MN-166 (ibudilast) did not affect cue- and stress-induced alcohol craving. However, MN-166 (ibudilast) increased positive mood during both the cue reactivity and stress procedures. MN-166 (ibudilast) was safe and well-tolerated during the study. In May 2018, we announced plans to initiate an NIH-funded clinical trial of MN-166 (ibudilast) in alcohol dependence and withdrawal in collaboration with researchers at UCLA. This study was a randomized, double-blind, placebo-controlled Phase 2 trial to evaluate the effect of 14 days of ibudilast treatment on mood, heavy drinking, and neural reward signals in 52 patients with alcohol use disorder (AUD). Positive results of this Phase 2 clinical trial were presented at the American Psychological Association 2020 Annual Convention which was held online in August 2020. Results from this clinical trial were published in June 2021 in Nature's *Translational Psychiatry* which included the following: (1) MN-166 (ibudilast) did not have a significant effect on negative mood; (2) MN-166 (ibudilast), relative to placebo, reduced the odds of heavy drinking across time by 45% ($p=0.04$); (3) MN-166 (ibudilast) attenuated alcohol cue-elicited activation in the ventral striatum (VS) (i.e. reduced the rewarding response to alcohol in the brain) compared to placebo ($p=0.01$); (4) alcohol cue-elicited activation in the VS predicted subsequent drinking in the MN-166 (ibudilast) group ($p=0.02$), such that individuals who had attenuated VS activation and took MN-166 (ibudilast) had the fewest number of drinks per drinking day in the week following the scan; and (5) MN-166 (ibudilast) reduced alcohol craving compared to placebo on non-drinking days ($p=0.02$). These findings extend preclinical and human laboratory studies of the utility of ibudilast to treat AUD and suggest a

biobehavioral mechanism through which ibudilast acts, namely, by reducing the rewarding response to alcohol cues in the brain leading to a reduction in heavy drinking. In August 2018, we announced a new NIAAA-funded Phase 2b clinical trial of MN-166 (ibudilast) in alcohol dependence in collaboration with researchers at UCLA. This clinical trial, which is currently ongoing, is evaluating has been completed, evaluated whether MN-166 (ibudilast) will would decrease the percentage of heavy drinking days (defined as ≥ 5 drinks for men and ≥ 4 drinks for women), as compared to placebo, over the course of the 12-week trial.

In February 2022, we announced that MN-166 (ibudilast) was discussed as one of the promising pharmacological agents for the treatment of AUD in the journal *Drugs*. The publication, which was written by researchers at UCLA, discussed the beneficial effects of MN-166 (ibudilast) in treating AUD and noted that these effects are thought to be driven by its anti-inflammatory and pro-neurotrophic properties. In April 2022, we announced that a secondary analysis of a Phase 2 clinical trial of MN-166 (ibudilast) in AUD was published in the journal *Alcoholism: Clinical and Experimental Research*. The publication, which was written by researchers at UCLA, discussed the results of the secondary analysis and noted that reductions in alcohol craving may represent a primary mechanism of MN-166 (ibudilast). In December 2022, we announced that positive results from a secondary analysis of a Phase 2 trial of MN-166 (ibudilast) in AUD were published in *The American Journal of Drug and Alcohol Abuse*. These results showed that the high baseline C-reactive protein (CRP) group, i.e. the participants with high inflammation, who received MN-166 (ibudilast) had significantly fewer drinks per drinking day compared to the low baseline CRP group who received MN-166 (ibudilast) (p = (p=0.007). In January 2023, we announced that the Phase 2b clinical trial of MN-166 (ibudilast) for the treatment of alcohol use disorder had completed enrollment. In June 2023, we announced results of the Phase 2b clinical trial of MN-166 (ibudilast) in alcohol use disorder which

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were presented at the 46th Annual Research Society on Alcoholism (RSA) Scientific Meeting. This study was a randomized, double-blind, placebo-controlled, Phase 2b clinical trial in 102 treatment-seeking men and women with moderate or severe alcohol use disorder. MN-166 (ibudilast) was not superior to placebo for the primary objective of reducing percent heavy drinking days. Also, MN-166 (ibudilast) was not superior to placebo for the secondary endpoints of 1) the number of drinks consumed per day, 2) the number of drinks consumed per drinking day, 3) the percentage of days abstinent, 4) the percentage of subjects with no heavy drinking days, and 5) the percentage of subjects who are abstinent. This trial showed a placebo effect in which both the placebo and MN-166 (ibudilast) decreased heavy drinking.

Chemotherapy-Induced Peripheral Neuropathy: Peripheral neuropathy is a set of symptoms caused by damage to peripheral nerves, the nerves that are away from the brain and spinal cord. Some of the chemotherapy and other drugs used to treat cancer can damage peripheral nerves which carry sensations to the brain and control the movement of the arms and legs. This damage results in chemotherapy-induced peripheral neuropathy (CIPN) which can be a disabling side effect of cancer treatment. Common symptoms of CIPN include pain, burning, tingling, loss of feeling, coordination and balance problems, muscle weakness, trouble swallowing and passing urine, constipation, and blood pressure changes. Severe CIPN may require chemotherapy dose reduction or cessation. According to a meta-analysis which included more than 4,000 patients, CIPN prevalence was 68% when measured in the first month after chemotherapy, 60% at 3 months, and 30% at 6 months or more (“Incidence, prevalence, and predictors of chemotherapy-induced peripheral neuropathy: A systematic review and meta-analysis,” Seretny M et al 2014). In March 2018, we announced plans to initiate a clinical trial to evaluate MN-166 (ibudilast) as a treatment for prevention of CIPN which was funded by the University of Sydney Concord Cancer

Centre in Australia. This open-label, sequential cross-over pilot study assessed acute neurotoxicity, CIPN, and drug interactions of MN-166 (ibudilast) in patients with metastatic gastrointestinal cancer (colorectal cancer and upper gastrointestinal cancers) who were receiving oxaliplatin. In September 2020, we announced that positive clinical findings from this clinical trial were published in *Cancer Chemotherapy and Pharmacology*. Co-administration of MN-166 (ibudilast) with oxaliplatin resulted in improvement or stabilization of oxaliplatin-induced neurotoxicity in the majority of participants treated with oxaliplatin. According to the Oxaliplatin-Specific Neurotoxicity Scale (OSNS) assessments, 12 out of 14 participants reported acute neurotoxicity (Grade 1 or 2) in both cycles. Of those, ten out of 12 participants were unchanged and two participants had improved symptoms from Grade 2 to Grade 1 with MN-166 (ibudilast) co-treatment. Acute neurotoxicity, which predicts chronic CIPN, is expected to worsen in patients with continued chemotherapy. Pharmacokinetic analysis indicated no effect of MN-166 (ibudilast) on systemic exposure of oxaliplatin. In October 2020, we announced plans to initiate a multi-center, placebo-controlled, randomized Phase 2b trial to evaluate MN-166 (ibudilast) in CIPN, which is funded by the Australasian Gastro-Intestinal Trials Group (AGITG). This clinical trial is evaluating MN-166 (ibudilast) as a potential treatment to reduce acute neurotoxicity severity and CIPN in patients with metastatic colorectal cancer.

Degenerative Cervical Myelopathy: Degenerative cervical myelopathy (DCM), also known as cervical spondylotic myelopathy, involves spinal cord dysfunction from compression in the neck. Degenerative cervical myelopathy 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 National Institute for Health Research (NIHR) in the United Kingdom (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, “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*. 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. Median survival According to the Glioblastoma Foundation, average life expectancy for glioblastoma patients who undergo treatment is approximately 11-15 12 - 15 months and only four months for adults with more aggressive glioblastoma (IDH-wildtype) those who do not receive standard treatment (surgery, temozolomide, and radiation therapy). 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 American Society of Clinical Oncology (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 Investigational New Drug

Application (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, Temodar-® 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 Macrophage Migration Inhibitory Factor (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 has 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 (Society for Brain Mapping and Therapeutics). 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 primary endpoints of this Phase 2 clinical trial were safety and tolerability of MN-166 (ibudilast) and temozolomide (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.

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*. 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 Acute Respiratory Distress Syndrome (ARDS) 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 August 2021, we announced completion of 75% of planned enrollment in this Phase 2 clinical trial. 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 intravenous (IV) infusion in healthy volunteers was completed with a favorable safety profile and was well tolerated.

Chlorine Gas-Induced Lung Injury: Chlorine gas is a toxic chemical that can be released in industrial accidents and terrorist attacks. Inhalation of chlorine gas causes damage to the respiratory tract and can result in acute lung injury. In March 2021, we announced a partnership with the Biomedical Advanced Research and Development Authority (BARDA), part of the Office of the Assistant Secretary Administration for Strategic Preparedness and Response at (ASPR) in the U.S. Department of Health and Human Services, to develop MN-166 (ibudilast) as a potential medical countermeasure (MCM) against chlorine gas-induced lung damage such as acute respiratory distress syndrome (ARDS) ARDS and acute lung injury (ALI). ALI. Under the Division of Research, Innovation, and Ventures' (DRIVe) Repurposing Drugs in Response to Chemical Threats (ReDIRECT) program, BARDA agreed to provide federal funding for proof-of-concept studies of MN-166 (ibudilast) in preclinical models of chlorine gas-induced acute lung injury under Contract No. 75A50121C00022. MN-166 (ibudilast) was the first compound to receive BARDA's development support through the DRIVe ReDIRECT program. In June

2021, September 2023, we announced initiation the results of a sheep the nonclinical studies conducted under our contract with BARDA. The primary endpoint of the first nonclinical efficacy study was the pulmonary function measure PaO2/FiO2, which is the ratio of arterial oxygen partial pressure to investigate fractional inspired oxygen. In the pilot design single-dose treatment regimen, MN-166 (ibudilast) in an ovine model high dose and the positive control rolipram were more efficacious than MN-166 (ibudilast) low dose and the negative control until 12 hours after chlorine exposure but this did not yield statistically significant results for overall pulmonary function. In the multi-dose study, each treatment was given every 12 hours with a total of chlorine-induced acute lung injury. Following treatment of 4 doses after the sheep chlorine gas challenge. Treatment with MN-166 (ibudilast) or high dose resulted in greater improvement (p=0.0001) in the mean PaO2/FiO2 ratio than MN-166 (ibudilast) low dose, rolipram, and the negative control. The mean PaO2/FiO2 ratio decreased (worsened) by 57% from 518.7 mmHg at baseline (the end of the chlorine gas exposure) to 224.8 mmHg at hour 48 in the negative control group. The mean PaO2/FiO2 ratio decreased (worsened) by 36% from 516.0 mmHg at baseline to 327.8 mmHg at hour 48 in the MN-166 (ibudilast) high dose group. At hour 48, the last time point measured in the study, will evaluate pulmonary function, the mean PaO2/FiO2 ratio was 46% higher (better) in the MN-166 (ibudilast) high dose group than in the negative control group (327.8 vs. 224.8 mmHg). Since ARDS is defined as a PaO2/FiO2 ratio less than 300 mmHg, the mean PaO2/FiO2 ratio values indicate that the negative control group was still categorized as having mild ARDS at the end of the 48-hour evaluation period but the MN-166 (ibudilast) high dose group had recovered enough to no longer be defined as having ARDS. MN-166 (ibudilast) was well tolerated and no safety concerns were observed in the first nonclinical efficacy study. After multiple attempts by our subcontractor to establish the feasibility of the second chlorine-gas induced lung injury model, it was not deemed to be a feasible model to evaluate a drug candidate and edema formation, cardiopulmonary hemodynamics, and systemic vascular permeability. In June 2021, we also announced a mouse study to investigate the there are no evaluable efficacy of MN-166 (ibudilast) in a murine model of chlorine-induced lung injury and lethality. After mice are exposed to chlorine gas and treated with MN-166 (ibudilast) or control, the study will evaluate survival, clinical outcomes, body weights, lung weights, and upper respiratory tract histopathology. In June 2022, we announced a modification to our contract with BARDA in which the contract was amended to extend the period of performance until March 2023. results.

Long COVID: Long COVID includes a wide range of ongoing respiratory, neurologic, and other symptoms that can last for weeks, months, or years following SARS-CoV-2 infection. According to the U.S. Centers for Disease Control and Prevention (CDC), the prevalence of long COVID is approximately 11% among adults reporting previous COVID-19. In August 2022, we announced plans to participate in RECLAIM (Recovering from COVID-19 Lingering Symptoms Adaptive Integrative Medicine Trial), a grant-funded, multi-center, randomized,

clinical trial to evaluate MN-166 (ibudilast) and other therapies for the treatment of Long COVID, the lingering symptoms of COVID-19. We reached an agreement to collaborate with the University Health Network, an academic health sciences center located in Toronto, which has the largest hospital-based research program in Canada. In February 2023, we announced that Health Canada completed its review of the clinical trial application and granted authorization to commence the RECLAIM trial.

trial and this study is ongoing.

MN-221 (bedoradrine)

MN-221 (bedoradrine) is a novel, highly selective beta-2-adrenergic receptor agonist which has been developed for the treatment of acute exacerbations of asthma. We licensed MN-221 (bedoradrine) from Kissei Pharmaceutical Co., Ltd. (Kissei) in February 2004. In October 2022, we terminated this license agreement and we now have no further financial obligation to Kissei. Current inhaled beta-agonist treatments for asthma exacerbations are limited by bronchoconstriction or insufficient airflow due to inflammation and airway constriction, which reduces the amount of inhaled drug that can get into the lungs. In addition, the amount of inhaled treatments a patient can tolerate is limited due to the potential for cardiovascular side effects (*e.g.* increased heart rate).

MN-221 (bedoradrine) is designed to treat acute exacerbations of asthma via intravenous (i.v.) infusion, bypassing constricted airways to deliver the drug to the lungs. Preclinical studies showed MN-221 (bedoradrine) to have a high affinity for the $ß_2$ -adrenergic receptor, found primarily in the lungs, and a much lower affinity for the $ß_1$ -adrenergic receptor found primarily in cardiac tissue. MN-221 (bedoradrine)'s improved delivery to the lungs and its cardiac safety profile has potential to help fill an unmet need for patients with acute exacerbations of asthma, helping them to breathe easier and avoid a costly hospital stay.

Acute Exacerbation of Asthma: According to the most recent data available from the United States National Center for Health Statistics, CDC, there were 1.84 million 939,000 emergency department visits due to asthma in 2019 2021 and 3,524 3,517 deaths due to asthma in 2019. 2021.

We completed a Phase 2b randomized, double-blind, placebo-controlled clinical trial which evaluated MN-221 (bedoradrine) in 175 patients with acute exacerbations of asthma in the emergency department setting. MN-221 (bedoradrine) did not statistically meet the primary endpoint, improvement in FEV1 (Forced Expiratory Volume in One Second) compared to placebo. However, MN-221 (bedoradrine) treatment demonstrated statistically significant improvements in endpoints associated with Dyspnea Index scores. MN-221 (bedoradrine) treatment significantly increased (improved) the change from baseline in Dyspnea Index scale score over Hours 0-3 compared to placebo (based on AUC [0-3 hr], p =0.0405) p=0.0405), significantly increased the change from baseline in Dyspnea Index scale scores at Hour 2 compared to placebo (based on mean score, p = p=0.0042), and significantly increased the percentage of subjects who

had improvement in the Dyspnea Index score ≥ 1 point at Hour 2 compared to placebo (p = (p=0.0323). A post-hoc analysis was performed to evaluate the Treatment Failure rate defined as the number of subjects who were either hospitalized or who returned to the emergency department during the course of the study. In subjects who received corticosteroids greater than 3 hours prior to study drug infusion, the number of treatment failures was significantly greater in the placebo group (74%) versus the MN-221 (bedoradrine) group (43%), p=0.0489. No safety/tolerability issues of clinical significance were observed.

In October 2012, we met with the FDA to review future development of this product candidate. The FDA identified the risk/benefit profile of MN-221 (bedoradrine) as a focal point for further development and advised that a clinical outcome, such as a reduction in hospitalizations, would need to be a primary endpoint in a pivotal trial. We have decided that any future MN-221 (bedoradrine) development will be designed based on the feedback received from the FDA and that any future MN-221 (bedoradrine) clinical trial development for asthma will be partner-dependent from a funding perspective.

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

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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

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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. In addition to granting MN-001 (tipelukast) Fast Track designation for the treatment of NASH with fibrosis, the FDA has also granted MN-001 (tipelukast) Orphan-Drug designation and Fast Track designation for the treatment of idiopathic pulmonary fibrosis (IPF).

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 (NASH) and Nonalcoholic Fatty Liver Disease (NAFLD): Nonalcoholic fatty liver disease (NAFLD) is a condition in which there is fat in the liver. Some individuals with NAFLD can develop nonalcoholic steatohepatitis (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 nonalcoholic fatty liver disease (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 pre-clinical 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. MN-001 (tipelukast) significantly reduced mean serum triglycerides by

135.7 mg/dL, resulting in a 41.3% reduction (p=0.02), which includes the data from the 15 subjects who completed eight weeks of treatment. Excluding one outlier with an extremely high triglyceride level of 1288 mg/dL before treatment, MN-001 (tipelukast) significantly reduced mean serum triglycerides by 74.9 mg/dL, resulting in a 28.8% reduction (p=0.00006). 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 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). 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 measured by MRI Proton Density Fat Fraction (MRI-PDFF) 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%).

Idiopathic Pulmonary Fibrosis (IPF): Pulmonary fibrosis (PF) is a progressive disease characterized by scarring of the lungs that thickens the lining, causing an irreversible loss of the tissue's ability to transport oxygen. The causes of PF vary and can be due to anti-cancer drug therapy or exposure to chemicals. Idiopathic pulmonary fibrosis (IPF) is one type of PF without a clear cause. According to the U.S. National Library of Medicine, IPF affects approximately 100,000 people in the United States, and 30,000 to 40,000 new cases are diagnosed annually. The prognosis for IPF is poor and most IPF patients survive only three to five years after diagnosis.

We completed a pre-clinical preclinical study evaluating the potential clinical efficacy of MN-001 (tipelukast) for the treatment of pulmonary fibrosis. MN-001 (tipelukast), which was administered orally once daily (30, 100 and 300 mg/kg) for two weeks, was evaluated in a mouse model of bleomycin-induced pulmonary fibrosis (PF) as

measured by CT evaluation of lung density, degree of pulmonary fibrosis using the Ashcroft score based on histopathological staining, and hydroxyproline content, which is an indicator of fibrosis or storage of collagen in

tissue. MN-001 (tipelukast) significantly decreased the Ashcroft score compared to the Vehicle-treated group (p<0.05) after two weeks of treatment and MN-001 (tipelukast) reduced lung density when compared to the Vehicle-treated group. Moreover, lung hydroxyproline content was significantly reduced compared to the Vehicle-treated group (p<0.01). These results show that treatment with MN-001 (tipelukast) has significant anti-fibrogenic effects in bleomycin-induced pulmonary fibrosis in mice.

We have an open IND and the FDA approved a Phase 2 clinical trial protocol for MN-001 (tipelukast) for the treatment of IPF. A Phase 2 clinical trial of MN-001 (tipelukast) in IPF was completed at Penn State and we announced results of this trial in August 2021. Although there were no clinically meaningful trends in favor of MN-001 (tipelukast) for the majority of the clinical outcome measures in this small study of 15 subjects, there were no worsening IPF events (acute IPF exacerbation or hospitalization due to respiratory symptoms) in the MN-001 (tipelukast) group compared to one worsening IPF event in the placebo group. MN-001 (tipelukast) demonstrated a substantial reduction in LOXL2, a biomarker for IPF, whereas LOXL2 increased in the placebo group. MN-001 (tipelukast) was safe and well tolerated. The FDA has granted Orphan-Drug designation to MN-001 (tipelukast) for treatment of IPF. Orphan-Drug designation will provide seven years of marketing exclusivity for MN-001 (tipelukast) for the treatment of IPF if it is approved for this indication. The FDA has also granted Fast Track designation to MN-001 (tipelukast) for the treatment of patients with IPF.

MN-029 (denibulin)

MN-029 (denibulin) is a novel tubulin binding agent (TBA) under development for the treatment of solid tumors. It exerts its activity through reversible inhibition of tubulin polymerization resulting in disruption of the cell cytoskeleton, which causes the cancer cells to deform in shape and ultimately leads to extensive central necrosis of the solid tumor. We licensed MN-029 (denibulin) from Angiogene Pharmaceuticals, Ltd. (Angiogene) in 2002.

Several preclinical pharmacology studies have assessed the mechanism of action and anti-tumor activity of MN-029 (denibulin) in vivo in rodent models of breast adenocarcinoma, colon carcinoma, lung carcinoma and KHT sarcoma. In these studies, MN-029 (denibulin) damaged poorly formed tumor blood vessels by weakening tumor blood vessel walls and causing leakage, clotting and eventual vascular shutdown within the tumor, in addition to the direct effect over tumor cells. These studies suggest that MN-029 (denibulin) acts quickly and is rapidly cleared from the body, which may reduce the potential for some adverse effects commonly associated with chemotherapy. Shutdown of tumor blood flow in tumor models was confirmed through the use of dynamic contrast-enhanced magnetic resonance imaging. In two Phase I clinical studies we conducted, MN-029 (denibulin) was well-tolerated at doses that reduced tumor blood flow.

The first Phase 1 trial determined the safety, tolerability, and maximum tolerated dose (MTD) level of single doses of MN-029 (denibulin) given every three weeks in 34 subjects with refractory cancer. The MTD was determined to be 180 mg/m^2 and appeared to be safe as a single i.v. dose administered every three weeks for as many as 25 cycles. There were no clinically significant changes in routine laboratory assessments, vital signs, or ECG monitoring. The most commonly reported adverse events (AEs) were similar to other chemotherapies - vomiting, nausea, diarrhea, and fatigue. There was a total of nine serious adverse events (SAEs) and study discontinuations due to AEs. In a preliminary evaluation of anti-tumor activity, no patient had a complete response or partial response; however stable disease was seen in 12 patients. MN-029 (denibulin) had a desired vascular effect in seven of 11 patients that were administered drug at dose levels of ≥120 mg/m^2. Nine patients continued into extended cycles of treatment.

The second Phase 1 study was conducted to determine the safety, tolerability and MTD of single doses of MN-029 (denibulin) given every seven days for a total of three doses (Days 1, 8 and 15), followed by 13-day

recovery (Days 16-28) in subjects with advanced/metastatic solid tumor cancer. Subjects who tolerated treatment with MN-029 (denibulin) could receive additional cycles. All 20 subjects reported at least one AE related to the study drug. The most common AEs considered related to the study drug were vomiting, nausea, arthralgia and

headache. There were no clinically significant changes in routine laboratory assessments, vital signs, or ECG monitoring. There was one SAE considered unrelated to the study drug. Consistent with the previous Phase 1 trial, MN-029 (denibulin) up to dose levels of 180 mg/m2 appeared to be safe and well tolerated. One subject had a partial response which lasted for 74 days. Stable disease was observed in seven subjects. The results suggested an effect of MN-029 (denibulin) on vascular perfusion; however, a larger sample size is warranted.

In January 2014, we were granted a new patent from the United States Patent and Trademark Office which covers MN-029 (denibulin) di-hydrochloride. The patent, which will expire no earlier than July 2032, has claims that cover a compound, pharmaceutical composition, and method of treating certain cell proliferation diseases, including solid tumors, based on denibulin di-hydrochloride. We have filed patent applications based on this U.S. patent in certain foreign countries, and most of them have been granted.

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

Indication	Clinical Study	Institution and Funding Agency(s)	Status
Long COVID	Recovering from COVID-19 Lingering Symptoms Adaptive Integrative Medicine (RECLAIM) Trial	Multicenter University Health Network	Ongoing

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 Progressive Multiple Sclerosis	A Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Safety, Tolerability and Activity of Ibudilast (MN-166) in Subjects with Progressive Multiple Sclerosis	Cleveland Clinic / Multicenter National Institute on Neurological Diseases and Stroke MediciNova, Inc.	Completed
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

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.	Ongoing
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
Chemotherapy-Induced Peripheral Neuropathy	A pilot study evaluating the impact of ibudilast on prevention of chemotherapy-induced acute neurotoxicity and evaluating pharmacokinetics with oxaliplatin in gastro-intestinal cancer patients receiving oxaliplatin	University of Sydney Concord Cancer Centre in Australia	Completed

Chemotherapy-Induced Peripheral Neuropathy	Can Oxaliplatin neurotoxicity be reduced with ibudilast in people with metastatic colorectal cancer – a phase II randomized study	University of Sydney Australasian Gastro-Intestinal Trials Group in Australia	Ongoing
Glioblastoma	Phase 1b/2a Multi-center, Open-label, Dose Escalation Study to Evaluate the Safety, Tolerability and Efficacy of MN-166 (ibudilast) and Temozolomide Combination Treatment in Patients With Glioblastoma	Dana-Farber Cancer Institute MediciNova, Inc.	Ongoing Completed
Substance Dependence / Addiction:			

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Methamphetamine Dependence	Randomized Trial of Ibudilast for Methamphetamine Dependence	UCLA National Institute on Drug Abuse	Completed

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Methamphetamine Dependence / Biomarker	Effect of Ibudilast on Neuroinflammation in Methamphetamine Users	Oregon Health & Science University	Ongoing

Opioid Dependence	Effects of Ibudilast (MN-166), a Glial Activation Inhibitor, on Oxycodone Self-Administration in Opioid Abusers	Columbia University / NYSPI National Institute on Drug Abuse MediciNova, Inc.	Completed
Alcohol Dependence	Development of Ibudilast (MN-166) as a Novel Treatment for Alcoholism	UCLA National Institute on Alcohol Abuse and Alcoholism	Completed
Alcohol Dependence and Withdrawal	Ibudilast (MN-166) and Withdrawal-Related Dysphoria	UCLA National Institute on Drug Abuse	Completed Ongoing Completed
Alcohol Dependence	Ibudilast (MN-166) for the Treatment of Alcohol Use Disorder	UCLA National Institute on Alcohol Abuse and Alcoholism	

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 32 28 issued U.S. patents and have filed 12 9 additional U.S. patent applications. We also hold 89 122 issued foreign patents and 31 28 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.

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 15 16 issued U.S. patents and 11 8 pending U.S. patent applications as well as 39 48 issued foreign patents and 23 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

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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

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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 neuropathic pain and it expires no earlier than December 2025. 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-221 (bedoradrine)

On February 25, 2004, we entered into an exclusive license agreement with Kissei for the development and commercialization of MN-221 (bedoradrine). In October 2022, we terminated this license agreement and we now have no further financial obligation to Kissei. Following termination of the license agreement, Kissei transferred to us the drug master file for MN-221 (bedoradrine), all related communications with FDA and all related ownership rights. We have no further obligations to Kissei in connection with developing and commercializing MN-221 (bedoradrine).

In addition to the previously licensed patents, we We have filed patent applications in the United States and certain foreign countries regarding additional uses and formulations of MN-221 (bedoradrine). We have been granted a U.S. patent which covers the use of MN-221 (bedoradrine) for the treatment of acute exacerbations of asthma and it expires no earlier than November 2030. This patent includes claims covering the use of MN-221 (bedoradrine) in combination with a standard of care treatment regimen and covers different routes of administration, including intravenous, oral and inhalation. We have been granted a U.S. patent that covers the use of MN-221 (bedoradrine) for the treatment of irritable bowel syndrome and it expires no earlier than April 2031.

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) and its active metabolite, MN-002, 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, and the United States composition of matter patent for MN-002 underlying the license expired on December 30, 2011. Foreign composition of matter patents for MN-001 (tipelukast) and MN-002 have also expired. We have been granted 14 own 9 U.S. patents and 41 65 foreign patents covering certain compositions, uses and manufacturing processes associated with MN-001 (tipelukast) and MN-002. 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'

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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.

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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.

MN-029 (denibulin)

On June 19, 2002, we entered into an exclusive license agreement with Angiogene, a privately held, British drug discovery company, for the development and commercialization of the ANG-600 series of compounds. We obtained an exclusive, worldwide, sub-licensable license to the patent rights and know-how related to the ANG-600 series of compounds disclosed in and included or covered by these patents for all indications. MN-029 (denibulin) is one of the ANG-600 series compounds covered by this license. We have been granted a U.S. patent which covers MN-029 (denibulin) di-hydrochloride and expires no earlier than July 2032. The allowed claims cover a compound, pharmaceutical composition and method of treating certain cell proliferation diseases, including solid tumors, based on denibulin di-hydrochloride. Patent applications corresponding to this U.S. patent were filed in certain foreign countries and patents have been granted in some of those countries.

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 at any time by giving 30 days' advance written notice to Angiogene.

The term of this agreement is determined on a country-by-country basis and extends until the earlier of the expiration of the last Angiogene patent (or equivalent) under license which has a valid claim or 15 years from the date of first commercial sale.

Under the license agreement, we have paid Angiogene $1.4 million to date and are obligated to make payments of up to $16.5 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.

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.

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.

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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), and Briumvi (ublituximab-xiiy) are approved for the treatment of secondary progressive MS with relapses. , 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. 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)

Our MN-166 (ibudilast) product candidate is also in development for the treatment of ALS. Generic riluzole, which is also sold under the brand names Rilutek and Tiglutik, Radicava (edaravone), and 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 Cytokinetics, BrainStorm Cell Therapeutics, AB Science, Biogen, Ionis Pharmaceuticals, Biohaven Pharmaceuticals, and Clene.

MN-166 (ibudilast) for Substance Dependence and Addiction

Our MN-166 (ibudilast) product candidate is also in development for the treatment of opioid dependence, methamphetamine addiction, and alcohol dependence. Current treatments for opioid withdrawal symptoms include narcotics such as generic methadone and Indivior, Inc.'s Suboxone Film (buprenorphine + the opioid antagonist naloxone). Other products approved for opioid dependence include Alkermes's Vivitrol (naltrexone monthly injection), Orexo's Zubsolv (buprenorphine and naloxone), and Indivior's Sublocade (buprenorphine extended-release injection). In December 2018, May 2023, Braeburn announced tentative FDA approval of BRIXADI an (buprenorphine) extended-release injection for subcutaneous use, a new weekly and monthly injectable buprenorphine product, medication for the treatment of moderate to severe opioid use disorder. In December 2022, Braeburn announced that the New Drug Application (NDA) resubmission for BRIXADI was accepted by the FDA disorder in patients who have initiated treatment with a PDUFA action date set for May 23, 2023. single dose of a transmucosal buprenorphine product or who are already being treated with a transmucosal buprenorphine-containing product. Limited non-narcotic drug candidates for opioid withdrawal symptoms exist. US WorldMeds, LLC's Lucemyra (lofexidine) is a central alpha-2 adrenergic agonist approved for mitigation of opioid withdrawal symptoms to facilitate abrupt opioid discontinuation. There are no pharmaceuticals currently approved for the treatment of methamphetamine addiction. InterveXion Therapeutics is developing a treatment for methamphetamine use disorder. Approved treatments for alcohol dependence include Antabuse (disulfiram), Vivitrol (naltrexone), and generic acamprosate. We are aware of additional treatments in development for the treatment of alcohol dependence use disorder at other companies including Opiant Indivior and Adial Pharmaceuticals.

MN-166 (ibudilast) for Chemotherapy-Induced Peripheral Neuropathy

Our MN-166 (ibudilast) product candidate is also in development for the treatment of chemotherapy-induced peripheral neuropathy. There are no pharmaceuticals currently approved for the treatment of chemotherapy-induced peripheral neuropathy. Duloxetine is sometimes used off-label for this indication. We are aware of treatments in development for the treatment of chemotherapy-induced peripheral neuropathy at other companies including AlgoTherapeutix (AlgoTx), Sonnet BioTherapeutics, and WinSanTor.

MN-166 (ibudilast) for Degenerative Cervical Myelopathy

Our MN-166 (ibudilast) product candidate is also in development for the treatment of degenerative cervical myelopathy. There are no pharmaceuticals currently approved for the treatment of degenerative cervical myelopathy.

MN-166 (ibudilast) for Glioblastoma

We have initiated clinical development of our MN-166 (ibudilast) product candidate for the treatment of 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 Laminar Pharmaceuticals. TVAX Biomedical.

MN-166 (ibudilast) for Prevention of Acute Respiratory Distress Syndrome (ARDS) ARDS in patients with COVID-19

Our MN-166 (ibudilast) product candidate is also in development for the 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 AstraZeneca. Rigel Pharmaceuticals.

31 MN-166 (ibudilast) for Long COVID

Our MN-166 (ibudilast) product candidate is also in development for the treatment of patients with Long COVID, the lingering symptoms of COVID-19. There are no pharmaceuticals currently approved for the treatment of Long COVID. We are aware of compounds in clinical development for the treatment of Long COVID at other companies including Axcella Therapeutics, AIM ImmunoTech, Tonix Pharmaceuticals, Humanetics, and Aerium Therapeutics.

MN-221 (bedoradrine) for Acute Exacerbations of Asthma

Our MN-221 (bedoradrine) product candidate has been developed for the treatment of acute exacerbations of asthma in the emergency room setting. The current standard of care for acute exacerbations of asthma is inhaled albuterol (a beta-2-adrenergic receptor agonist), inhaled ipratropium (an anticholinergic) and oral or injected corticosteroids. In addition, subcutaneously administered terbutaline (a beta-2-adrenergic receptor agonist) is sometimes used to treat this condition, particularly in pediatric patients.

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

Our MN-001 (tipelukast) product candidate has been developed for the treatment of NASH and NAFLD. There are currently no pharmaceuticals approved for the treatment of NASH or NAFLD. We are aware of compounds in clinical development for the treatment of NASH or NAFLD at other companies including Intercept Pharmaceuticals, Galectin Therapeutics, Gilead Sciences, Galmed Pharmaceuticals, Bristol-Myers Squibb, Pfizer, Novartis, Novo Nordisk, Merck, and Madrigal Pharmaceuticals.

MN-001 (tipelukast) for Idiopathic Pulmonary Fibrosis (IPF)

Our MN-001 (tipelukast) product candidate is in development for the treatment of IPF. Products approved in the United States for treatment of IPF include Roche's (formerly InterMune) Esbriet (pirfenidone) and Boehringer Ingelheim's

OFEV (nintedanib). Companies working on clinical development programs for treatment of IPF include Roche, United Therapeutics, and FibroGen. Bristol-Myers Squibb.

MN-029 (denibulin) for Solid Tumor Cancer

Our MN-029 (denibulin) product candidate has been developed for the treatment of solid tumor cancers. Roche's Kadcyla, a HER2-targeted antibody and microtubule inhibitor conjugate, is approved for treatment of patients with HER2-positive metastatic breast cancer who previously were treated with trastuzumab and a taxane. Bayer's Stivarga, a kinase inhibitor approved for metastatic colorectal cancer, was also approved for patients with advanced, unresectable (not subject to surgical removal) or metastatic gastrointestinal stromal tumor. Other drugs approved for solid tumor cancers include Roche's Avastin and Xeloda, Amgen's Xgeva, Pfizer's Sutent, and Novartis's Afinitor. We are aware of additional compounds in development for the treatment of solid tumor cancers at companies including Eli Lilly, Roche, Novartis, Pfizer, Sanofi, Amgen, Bayer, Merck, AstraZeneca, AbbVie and Bristol-Myers Squibb.

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

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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, or 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 produ 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 an 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 ar 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 i 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: 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

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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 Patent Term Restoration and marketing exclusivity: 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 United States Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may 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 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 13 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 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 year years ended December 31, 2022 December 31, 2023 and 2021, 2022, we had a net loss of $14.1 million $8.6 million and $10.1 million. $14.1 million, respectively. As of December 31, 2022 December 31, 2023 and December 31, 2021 December 31, 2022, our accumulated deficit was $407.1 million $415.7 million and $393.1 million. $407.1 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, 2022 December 31, 2023, we had available cash and cash equivalents of $18.5 million, investments of $40.0 million $51.0 million and working capital of $55.8 million $47.9 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;

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- 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;

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- 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; a
- the costs of establishing or contracting for sales and marketing capabilities and commercialization activities if we obta regulatory approval to market our product candidates.

We expect our research and development expenses to increase moderately in 2023 2024 relative to 2022 2023 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. These ownership changes 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 not completed an conducted a study and determined that, through December 31, 2022, no ownership change analysis changes have occurred. There is a risk that additional changes in ownership have occurred since 2011. 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.

We expect to manage the maturities of our investments to be able to fund our cash needs for operations and, as As of the date of this report, we believe we have sufficient working capital to fund operations at least through the end of 2024. 2025. 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 at least 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 FDA and comparable regulatory authorities in other countries. We are not permitted to market any of our product candidates in the United States 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. 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 to 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. For example, we may not be able replicate the positive results from our Phase 2 trial of MN-166 (ibudilast) in alcohol use disorder in clinical trials for other indications in the future. 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.

39 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 NASH, NAFLD and IPF 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, NAFLD and IPF. 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. INDs 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 regulator 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 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 inspectior 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.

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 IPF, NASH with fibrosis and MN-166 (ibudilast) for the potential treatment of progressive MS, the potential treatment of ALS, and the potential treatment of methamphetamine dependence 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 and as adjunctive therapy to temozolomide for the potential treatment of glioblastoma, and to MN-001 (tipelukast) for the potential treatment of IPF. 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

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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 for one or more of our current or future product candidates. Under FDA policies, a product candidate is eligible for priority review, or review within a six-month time frame from the time a complete NDA is accepted

for filing, 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 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 CROs, and trial sites, th 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, la 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
- 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 hol 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 othe 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 protocol

- 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 clinica 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, leadir 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.

The ongoing COVID-19 global pandemic has adversely impacted and may materially and adversely impact our business and operations. Any other illness or communicable disease, or any other public health crisis, could also adversely affect our business, results of operations and financial condition.

In December 2019, an outbreak of COVID-19 began and, in March 2020, the World Health Organization declared COVID-19 a pandemic. The COVID-19 pandemic has negatively impacted the global economy, disrupted global supply chains and created significant volatility and disruption of financial markets. In addition, in response to the COVID-19 pandemic, many state, local and foreign governments put in place quarantines, executive orders, shelter-in-place orders and similar government orders and restrictions in order to control the spread of the disease. Such orders or restrictions resulted in business closures, work stoppages, slowdowns and delays, work-from-home policies, travel restrictions and cancellation of events, among other effects that impacted our business, personnel, personnel at third-party manufacturing facilities and the availability or cost of materials. The ongoing COVID-19 global pandemic has adversely impacted and may materially and adversely impact our business and operations. For

example, 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 pandemic. We could be negatively impacted by any other illness or communicable disease, or any other public health crisis that, like COVID-19 pandemic, results in economic and trade disruptions, including the disruption of global supply chains.

The ultimate impact of the COVID-19 pandemic is highly uncertain and subject to sudden change, despite expiration of most of the mandates and a waning effect of the pandemic. Any future impacts could have a material, adverse impact on our liquidity, capital resources, operations and business and those of the third parties we rely on, and could worsen over time. The extent of the impact of the COVID-19 pandemic on our financial condition, liquidity, and future results of operations, including our ability to continue to advance our product development programs in the expected time frame, will depend on future developments, including the duration and spread of the pandemic and related restrictions on travel and transports, all of which are uncertain and cannot be predicted. While we do not yet know the full extent of the potential future impacts on our business, any of these occurrences could significantly harm our business, results of operations and financial condition. An extended period of global supply chain and economic disruption could also materially affect our business, results of operations, access to sources of liquidity and financial condition.

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, or 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 the ongoing COVID-19 pandemic. 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. The COVID-19 pandemic and government measures taken in response 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

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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 ongoing COVID-19 pandemic 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 current good manufacturing practices, or cGMPs and, in some cases, International Convention on Harmonization, or 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 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, or 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 healthcare 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 and Chief Executive Officer, 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 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 U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations. We can face serious consequences for violations.

U.S. 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 U.S. government and administered by the U.S. Departments of State, Commerce, and Treasury. U.S. export control laws may require a license or other authorization to export products to certain destinations and end users. In addition, U.S. 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, U.S. 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

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government-affiliated hospitals, universities, and other organizations. We also expect our non-U.S. 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, as well as rules and regulations implemented by the SEC, the NASDAQ Nasdaq Stock Market or NASDAQ, (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. Our listing obligations under the Standard Market of the Tokyo Stock Exchange, or TSE, also require that we comply either with Section 404 of the Sarbanes-Oxley Act 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, 2022 December 31, 2023 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, 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, in July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas. 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.

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 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, resulting from health epidemics, including the COVID-19 pandemic, unfavorable market conditions, regulatory and policy changes,and ongoing geopolitical matters, 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.

While the severity of the COVID-19 pandemic has lessened significantly, the pandemic has had a significant negative impact on the macroeconomic environment, such as 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 is a resurgence in the COVID-19 pandemic, or other health epidemics or outbreaks, 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.

Inflation 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, 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, increas 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, a 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 no 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), MN-001 (tipelukast), and MN-221 (bedoradrine) 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), MN-001 (tipelukast), and MN-221 (bedoradrine) 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), MN-001 (tipelukast), and MN-221 (bedoradrine) although we have a compound patent for MN-029.

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. For example, certain annuities were not paid in a timely manner with respect to foreign patents licensed under MN-002 (the active metabolite of MN-001 (tipelukast) and, as a result, our patent rights may be impaired in those territories. 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 U.S. 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 U.S. 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 U.S. 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 U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. These include allowing third-party submission of prior art to the 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 U.S. 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 U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

The U.S. federal government retains certain rights in inventions produced with its financial assistance under the 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 infringeme 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;
- 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 Nasdaq Global Market and the Standard Market of the Tokyo Stock Exchange in Japan, trading volume in our securities has been light and an active trading market may not develop for our common stock. In 2022, 2023, our average trading volume was approximately 61,378 44,278 shares per day on the NASDAQ Global Market and approximately 67,690 100,325 shares per day on the Standard Market.

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, 2022 December 31, 2023, our common stock has traded as high as approximately $42.00 and as low as approximately $1.30. 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 development 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, including conditions resulting from COVID-19;
- 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 safe 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 on the NASDAQ 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 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.

The sale of additional common stock, including under our existing shelf registration statement and at market issuance sales agreement may cause substantial dilution to our existing stockholders and/or the price of our common stock to decline.

Sales of a substantial number of shares of our common stock could cause our stock price to decline. Sales of a substantial number of shares of our common stock could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. As of February 13, 2023 February 12, 2024, we had 49,046,246 shares of common stock outstanding. Shares held by directors, executive officers and other affiliates will be subject to volume limitations under Rule 144 under the Securities Act and various vesting agreements.

Further, we have registered and intend to continue to register all shares of common stock that we may issue under our equity compensation plans. Once we register these shares, they can be freely sold in the public market

upon issuance, subject to volume limitations applicable to affiliates. We cannot predict what effect, if any, sales of our shares in the public market or the availability of shares for sale will have on the market price of our common stock. However, future sales of substantial amounts of our common stock in the public market, including shares issued upon exercise of our outstanding warrant or options, or the perception that such sales may occur, could adversely affect the market price of our common stock. We also expect that significant additional capital may be needed in the future to continue our planned operations.

On August 26, 2022, we filed a shelf registration statement (Shelf Registration Statement) on Form S-3 with the SEC (that was declared effective by the SEC on September 6, 2022), which permits us to offer up to $200.0 million of our common stock, preferred stock, debt securities and warrants in one or more offerings and in any combination, including units from time to time. Our Shelf Registration Statement is intended to provide us with flexibility to raise capital in the future for general corporate purposes. As part of this Shelf Registration Statement, we also entered into an amendment to an at market issuance sales agreement (as amended, the "ATM Agreement") ATM Agreement) with B. Riley Securities, Inc. (formerly B. Riley FBR, Inc.) (B. Riley Securities) pursuant to which we may offer and sell common stock through B. Riley Securities from time to time up to an aggregate offering price of $75.0 million, of which $10.3 million of our common stock was sold under a previous shelf registration statement on Form S-3, which expired on August 22, 2022 (Prior Shelf Registration Statement). In connection with the ATM Agreement and as part of the Shelf Registration Statement, we filed a

prospectus supplement to register up to $64.7 million of our common stock, which represents the remaining shares that we previously registered for sale under the sales agreement and the Prior Shelf Registration Agreement. From time to time, we may sell additional shares of our common stock under the Shelf Registration Statement or the ATM Agreement. Depending upon market liquidity at the time, sales of shares of our common stock under the Shelf Registration Statement or the ATM Agreement may cause the trading price of our common stock to decline and may result in substantial dilution to the interests of other holders of our common stock. The sale of a substantial number of shares of our common stock, including under the Shelf Registration Statement or the ATM Agreement, or anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to sell equity or equity-related securities.

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, 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, 2023, 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 the 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 discriminato 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, 2023, 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 now 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 2021 2023 and has a term of two years with an auto-renewal, two year extension. 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 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 Nasdaq Global Market and trades under the symbol "MNOV."

Holders of Common Stock

As of February 13, 2023 February 12, 2024, there were approximately 11 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.

On January 29, 2021, we sold and issued to an investor 3,656,307 shares of our common stock at a price of $5.47 per share for approximately $20 million in cash proceeds, net of approximately $0.1 million in issuance costs, in a private placement pursuant to the terms and conditions of a Securities Purchase Agreement dated as of January 11, 2021 by and between us and such investor.

Such shares were sold and issued without registration under the Securities Act in reliance on the exemptions provided by Section 4(a)(2) of the Securities Act as transactions not involving a public offering and Rule 506 promulgated under the Securities Act as sales to accredited investors, and in reliance on similar exemptions under applicable state laws.

On January 29, 2021 we filed a Registration Statement on Form S-3 to register the 3,656,307 shares of our common stock held by the investor for the resale or other disposition of such shares (Resale Registration Statement). The Resale

Registration Statement was declared effective by the SEC on February 10, 2021. 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, substance dependence and addiction (e.g., methamphetamine dependence, opioid dependence, and alcohol dependence), and prevention of acute respiratory distress syndrome (ARDS), and Long COVID, and MN-001 (tipelukast) for fibrotic and other diseases such as nonalcoholic fatty liver disease (NAFLD) and idiopathic pulmonary fibrosis (IPF). Our pipeline also includes MN-221 (bedoradrine) for the treatment of acute exacerbation of asthma and MN-029 (denibulin) for solid tumor cancers. We were incorporated in Delaware in September 2000.

We have incurred significant net losses since our inception. For the year ended December 31, 2022 December 31, 2023, we had a net loss of $14.1 million $8.6 million. At December 31, 2022 December 31, 2023, from inception, our accumulated deficit was $407.1 million $415.7 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.

Impact of the ongoing COVID-19 Pandemic on our Business

The ongoing COVID-19 pandemic has resulted and is likely to continue to result, in significant national and global economic disruption and has, and may continue to adversely affect our business. To date, we have experienced certain adverse effects on our business as well as been provided certain opportunities as a result of the pandemic. The pandemic caused 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 pandemic. However, we have seen an increase in the number of patient visits compared to earlier in the pandemic and we continue to enroll patients in clinical trials. Throughout the pandemic, we have continued with routine clinical trial activities including executing new clinical trial agreements, negotiating budgets, institutional review board (IRB) approvals, site training, and other activities related to the initiation of new clinical trials and the opening of new clinical trial sites, although some of these activities took longer to complete than what we experienced prior to the pandemic.

The pandemic created certain opportunities for our clinical development and we have pursued those opportunities. Following the outbreak of the pandemic, we designed a clinical trial to evaluate MN-166 (ibudilast) for prevention of acute respiratory distress syndrome (ARDS) ARDS caused by COVID-19. In June 2022, we announced positive top-line results from this Phase 2 clinical trial in which MN-166 (ibudilast) demonstrated large improvements compared to placebo for all four clinical endpoints analyzed. Separately, in August 2022, we announced plans to participate in RECLAIM (Recovering from COVID-19 Lingering Symptoms Adaptive Integrative Medicine Trial), a grant-funded clinical trial to evaluate MN-166 (ibudilast) and other therapies for the treatment of Long COVID, the lingering symptoms of COVID-19. In February 2023, we announced that Health

Canada completed its review of the clinical trial application and granted authorization to commence the RECLAIM trial.trial and this study is ongoing.

We continue to actively monitor the pandemic situation and the possible effects on its our financial condition, liquidity, operations, suppliers, industry, and workforce.

Critical Accounting Policies and Use of 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 accrued liabilities. 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.

Research, Development and Patent Expenses and Accrued Liabilities

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. 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,		Year Ended December 31,	
	2022	2021	2023	2022
External development expense:				
MN-221	$ 465	$ 11	$ 16	$ 465
MN-166	6,387	5,962	2,837	6,387
MN-001	194	192	552	194
MN-029	3	3	4	3
Other	11	28	—	11
Total external development expense	7,060	6,196	3,409	7,060
R&D personnel expense	1,433	1,378	1,553	1,433
R&D facility and depreciation expense	58	47	58	58
Patent expense	388	438	400	388
Other R&D expense	205	479	238	205
Total research, development and patent expense	$ 9,144	$ 8,538	$ 5,658	$ 9,144

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, 2023, the Company 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 its 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, 2023. If the Company experiences a sustained decline in its stock price or other material changes in the significant assumptions that affect the determination of the fair value of the Company's 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, 2022 December 31, 2023 and 2021 2022

Revenues

Revenues were $0.0 million $1.0 million and $4.0 million $0.0 million for the year years ended December 31, 2022 December 31, 2023 and 2021, 2022, respectively. The decrease increase of $4.0 million $1.0 million was due to the receipt of two a milestone payments in 2021 payment under an agreement with Genzyme Corporation.

Research, Development and Patent Expenses

Research, development and patent expenses for the year ended December 31, 2022 increased December 31, 2023 decreased by $0.6 million $3.4 million to $9.1 million $5.7 million as compared to $8.5 million $9.1 million for the prior year, primarily due to an increase a decrease in MN-166 and MN-221 expenses. The decrease in MN-166 expenses is primarily due to decreased study expenses based on patient enrollment and study completion timelines in 2023 compared to 2022,

as well as the receipt of a $0.7 million payment from the Biomedical Advanced Research and Development Authority (BARDA) to partially reimburse us for preclinical study costs, which was recorded as an offset to MN-166 research and development expense in 2023. The decrease in MN-221 expenses is primarily related expenses to a fee we paid in 2022 to Kissei Pharmaceutical co., Ltd. (Kissei) in connection with terminating a license agreement.

General and Administrative

General and administrative expenses for the year ended December 31, 2022 December 31, 2023 decreased by $0.2 million $0.3 million to $5.5 million $5.2 million compared to $5.7 million $5.5 million for the prior year, primarily driven by a decrease in stock compensation expense for performance-based stock options, partially offset by increased compensation costs and increased accounting expenses.

Other Expense, net

Other expense for the years ended 2022 2023 and 2021 2022 was approximately $247,000 $0.5 million and $59,000, $0.2 million, respectively. Other expense consisted The increase of $0.3 million was primarily driven by penalties on early disposal of bank certificates of deposit, interest expense, and net transaction losses related to vendor invoices denominated in foreign currencies.deposit.

Interest Income

Interest income for the year ended December 31, 2022 December 31, 2023 increased by $0.7 million $1.0 million to $0.8 million $1.8 million compared to $0.1 million $0.8 million for the prior year, primarily driven by higher interest rates on cash and bank certificates of deposit. Interest income consists of interest earned on our cash and cash equivalents and investments.

Liquidity and Capital Resources

We incurred losses of $14.1 million $8.6 million and $10.1 million $14.1 million for the years ended December 31, 2022 December 31, 2023 and 2021, 2022, respectively. At December 31, 2022 December 31, 2023, our accumulated deficit was $407.1 million $415.7 million as compared to $393.1 million $407.1 million for the year ended December 31, 2021 December 31, 2022. 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, 2022 December 31, 2023 and 2021 2022 (in thousands):

	2022	2021	2023	2022
Net cash (used in) provided by:				
Operating activities	(12,912)	(9,382)	(7,431)	(12,912)
Investing activities	(40,005)	(29)	39,908	(40,005)
Financing activities	8	20,778	—	8

Total	$ (52,909)	$ 11,367	$ 32,477	$ (52,909)

Factors That May Affect Future Financial Condition and Liquidity

As of December 31, 2022 December 31, 2023, we had available cash and cash equivalents of $18.5 million, investments of $40.0 million $51.0 million and working capital of $55.8 million $47.9 million. For the year ended December 31, 2022, we used net cash in investing activities to purchase investments, consisting of bank certificates of deposit with original purchased maturities of between seven and 13 months, to take advantage of higher market interest rates to provide increased interest income. We expect to manage the maturities of our investments to be able to fund our cash needs for operations and, as As of the date of this report, we believe we have sufficient working capital to fund operations at least through the end of 2024. 2025. This is based on our expected operating cash needs for 2023 2024 to be approximately $21.2 million $19.2 million and assuming we keep our spend at a similar level for 2024 2025 including expected inflation increases. We expect that this level of operating spend will be sufficient to meet the businesses needs for research and development to help monetize our products 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; a
- the costs of establishing or contracting for sales and marketing capabilities and commercialization activities if we obta regulatory approval to market any of our product candidates.

At December 31, 2022 December 31, 2023, 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 filed a shelf registration statement (Shelf Registration Statement) on Form S-3 with the SEC (that was declared effective by the SEC on September 6, 2022), which permits us to offer up to $200.0 million

of our common stock, preferred stock, debt securities and warrants in one or more offerings and in any combination, including units from time to time. Our Shelf Registration Statement is intended to provide us with flexibility to raise capital in the future for general corporate purposes. As part of this Shelf Registration Statement, we also 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) pursuant to which we may offer and sell common stock through B. Riley Securities from time to time up to an aggregate offering price of $75.0 million, of which $10.3 million of our common stock was sold under a previous shelf registration statement on Form S-3, which expired on August 22, 2022 in August 2022 (Prior Shelf Registration Statement). In connection with the ATM Agreement and as part of the Shelf Registration Statement, we filed a

prospectus supplement to register up to $64.7 million of our common stock, which represents the remaining shares that we previously registered for sale under the sales agreement and the Prior Shelf Registration Agreement.

Sales of our common stock through B. Riley Securities, 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. B. Riley Securities may also sell the common stock in privately negotiated transactions, subject to our prior approval. We agreed to pay B. Riley Securities an aggregate commission rate of up to 3.5% 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 B. Riley Securities and the per share purchase price of each transaction.

No shares of common stock were sold under the ATM agreement for the years ended December 31, 2022 December 31, 2023 and December 31, 2021 December 31, 2022.

For the year ended December 31, 2021, we sold and issued 3,656,307 shares of our common stock at a price of $5.47 per share for approximately $20 million in gross proceeds in a private placement of stock on January 29, 2021. These proceeds are used for the normal operating expenses of the business including increased R&D activities.

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, 2022 December 31, 2023, our contractual commitments for our leases were $0.7 million $0.6 million, which will be paid over the lease term.

Milestone Obligations

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. 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, 2022 December 31, 2023 and 2021, 2022, 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, 2022 December 31, 2023 and 2021, 2022, 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, clinical site activations or vendor information of actual

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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, 2022 December 31, 2023, the Company recorded $1.5 million $1.0 million in clinical trial accruals.

We identified the clinical trial accruals as a critical audit matter due to significant management judgment 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 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 obtaining and inspecting significant agreements and agreement amendments, evaluating the Company's documentation of trial progress and status (including consideratic

of measures such as patient enrollment and milestones achieved), and testing a sample of transactions and comparir the costs against related invoices and contracts.

- 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 significant on-going clinical trials.

- Testing a sample of subsequent payments to evaluate the completeness of clinical trial accruals at the end of the yea

/s/ BDO USA, LLP P.C.

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

San Diego, California

February 16, 2023 15, 2024

MEDICINOVA, INC.

CONSOLIDATED BALANCE SHEETS

	December 31,		December 31,	
	2022	2021	2023	2022
Assets:				
Current assets:				
Cash and cash equivalents	18,505,493	71,430,954	$ 50,999,442	$ 18,505,493
Prepaid expenses and other current assets	499,403	577,992	174,938	499,403
Investments	39,982,213	—	—	39,982,213
Total current assets	58,987,109	72,008,946	51,174,380	58,987,109

Goodwill	9,600,240	9,600,240	9,600,240	9,600,240
In-process research and development	4,800,000	4,800,000	4,800,000	4,800,000
Property and equipment, net	45,269	57,565	45,800	45,269
Right-of-use asset	629,495	824,215	575,406	629,495
Other non-current assets	92,792	115,492	74,151	92,792
Total assets	$ 74,154,905	$ 87,406,458	$ 66,269,977	$ 74,154,905
Liabilities and Stockholders' Equity				
Current liabilities:				
Accounts payable	$ 424,646	$ 402,740	$ 1,003,937	$ 424,646
Accrued liabilities and other current liabilities	2,605,308	2,298,203	2,059,238	2,605,308
Operating lease liability	157,505	131,965	215,926	157,505
Total current liabilities	3,187,459	2,832,908	3,279,101	3,187,459
Deferred tax liability	201,792	201,792	201,792	201,792
Other non-current liabilities	523,619	694,674	410,660	523,619
Total liabilities	3,912,870	3,729,374	3,891,553	3,912,870
Commitments and contingencies (Note 5)				
Stockholders' equity:				
Common stock, $0.001 par value; 100,000,000 shares authorized at December 31, 2022 and December 31, 2021; 49,046,246 and 49,043,246 shares issued and outstanding at December 31, 2022 and December 31, 2021, respectively	49,046	49,043		

Common stock, $0.001 par value; 100,000,000 shares authorized at December 31, 2023 and December 31, 2022; 49,046,246 and 49,046,246 shares issued and outstanding at December 31, 2023 and December 31, 2022, respectively			49,046	49,046
Additional paid-in capital	477,438,451	476,788,012	478,149,161	477,438,451
Accumulated other comprehensive loss	(115,285)	(98,877)	(118,090)	(115,285)
Accumulated deficit	(407,130,177)	(393,061,094)	(415,701,693)	(407,130,177)
Total stockholders' equity	70,242,035	83,677,084	62,378,424	70,242,035
Total liabilities and stockholders' equity	$ 74,154,905	$ 87,406,458	$ 66,269,977	$ 74,154,905

See accompanying notes to consolidated financial statements.

MEDICINOVA, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	Years ended December 31,		Years ended December 31,	
	2022	2021	2023	2022
Revenues	$ —	$ 4,037,500	$ 1,000,000	$ —
Operating expenses:				
Research, development and patents	9,143,792	8,538,027	5,657,895	9,143,792

General and administrative	5,484,857	5,715,285	5,242,370	5,484,857
Total operating expenses	14,628,649	14,253,312	10,900,265	14,628,649
Operating loss	(14,628,649)	(10,215,812)	(9,900,265)	(14,628,649)
Interest income	809,673	143,626	1,834,665	809,673
Other expense, net	(247,285)	(59,498)	(502,869)	(247,285)
Loss before income taxes	(14,066,261)	(10,131,684)	(8,568,469)	(14,066,261)
Income tax expense	(2,822)	(2,568)	(3,047)	(2,822)
Net loss applicable to common stockholders	$ (14,069,083)	$ (10,134,252)		
Net loss			$ (8,571,516)	$ (14,069,083)
Basic and diluted net loss per common share	$ (0.29)	$ (0.21)	$ (0.17)	$ (0.29)
Shares used to compute basic and diluted net loss per common share	49,045,342	48,596,255	49,046,246	49,045,342
Net loss applicable to common stockholders	$ (14,069,083)	$ (10,134,252)		
Net loss			$ (8,571,516)	$ (14,069,083)
Other comprehensive loss, net of tax:				
Foreign currency translation adjustments	(16,408)	(10,658)	(2,805)	(16,408)
Comprehensive loss	$ (14,085,491)	$ (10,144,910)	$ (8,574,321)	$ (14,085,491)

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, 2020	45,024,560	$ 45,025	$ 454,296,536	$ (88,219)	$ (382,926,842)	$ 71,326,500
Share-based compensation	—	—	1,717,513	—	—	1,717,513

Issuance of shares under an employee stock purchase plan (ESPP)	1,42 4	2	6,10 8	—	—	6,1 10 19,8 81,6 32 89 0
Issuance of common stock in a private placement transaction, net of issuance costs	3,65 6,30 7	3,6 5 6	19,8 77,9 76	—	—	81,6 32,2 89 0
Issuance of common stock for option exercises	36,95 5	0	88,9 9	—	—	2,3 9 (10,1 0,13 4,25 5)
Net loss	—	—	—	—	(2)	(2)

Foreign currency translation adjustments	—	—	—	(10,658)	—	(10,658)						
Balance at December 31, 2021	49,043,246	$ 49	$ 476,788,012		$ (98,877)	$ (393,061,094)	$ 83,677,084					
Share-based compensation	—	—	642,522	—	—	642,522	—	—	642,522	—	—	642,522
Issuance of common stock for option exercises	3,000	3	7,917	—	—	7,920						

Net loss	—	—	—	—	(14,069,083)	(14,069,083)	—	—	—	—	(14,069,083)	(14,069,083)
Foreign currency translation adjustments	—	—	—	(16,408)	—	(16,408)	—	—	—	(16,408)	—	(16,408)
Balance at December 31, 2022	49,046,246	$ 6	$ 1	$ (85)	$ (77)	$ 5	49,046,246	49,046	477,438,451	(115,285)	(407,130,177)	70,242,035
Share-based compensation							—	—	710,710		—	710,710
Net loss							—	—	—	—	(8,571,516)	(8,571,516)
Foreign currency translation adjustments							—	—	—	(2,805)	—	(2,805)

Balance at December 31, 2023	49,046,246	$ 49,046	$ 478,149,161	$ (118,090)	$ (415,701,693)	$ 62,378,424

See accompanying notes to consolidated financial statements.

MEDICINOVA, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years ended December 31,	
	2022	**2021**
Operating activities:		
Net loss	$ (14,069,083)	$ (10,134,252)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash stock-based compensation	642,522	1,717,513
Depreciation and amortization	17,707	26,149
Non-cash interest on investments	(154,003)	—
Loss on disposal of investments	122,475	—
Loss on disposal of property and equipment	—	286
Change in carrying amount of right-of-use asset	194,719	216,640
Changes in assets and liabilities:		
Prepaid expenses and other assets	150,605	50,319
Accounts payable, accrued liabilities and other liabilities	329,010	(1,026,525)
Operating lease liabilities	(145,515)	(231,735)
Net cash used in operating activities	(12,911,563)	(9,381,605)
Investing activities:		
Purchases of investments	(59,877,526)	—
Proceeds from disposal of investments	19,877,526	—

Acquisitions of property and equipment	(5,010)	(28,732)
Net cash used in investing activities	(40,005,010)	(28,732)
Financing activities:		
Proceeds from issuance of common stock and exercise of common stock options	7,920	20,890,239
Common stock issuance costs	—	(118,368)
Proceeds from issuance of equity under ESPP	—	6,110
Net cash provided by financing activities	7,920	20,777,981
Effect of exchange rate changes on cash and cash equivalents	(16,808)	26,547
Net change in cash and cash equivalents	(52,925,461)	11,394,191
Cash and cash equivalents, beginning of year	71,430,954	60,036,763
Cash and cash equivalents, end of year	$ 18,505,493	$ 71,430,954
Supplemental disclosure of cash flow information:		
Right-of-use asset obtained in exchange for operating lease liability	$ —	$ 870,373

	Years ended December 31,	
	2023	2022
Operating activities:		
Net loss	$ (8,571,516)	$ (14,069,083)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash stock-based compensation	710,710	642,522
Depreciation and amortization	20,295	17,707
Non-cash interest on investments	(346,390)	(154,003)
Loss on disposal of investments	448,903	122,475
Loss on disposal of property and equipment	472	—
Change in carrying amount of right-of-use asset	194,502	194,719
Changes in assets and liabilities:		
Prepaid expenses and other assets	287,628	150,605
Accounts payable, accrued liabilities and other liabilities	19,238	329,010
Operating lease liabilities	(194,880)	(145,515)
Net cash used in operating activities	(7,431,038)	(12,911,563)
Investing activities:		
Purchases of investments	—	(59,877,526)
Proceeds from disposal of investments	39,929,015	19,877,526
Acquisitions of property and equipment	(21,299)	(5,010)
Net cash provided by (used in) investing activities	39,907,716	(40,005,010)

Financing activities:		
Proceeds from issuance of common stock and exercise of common stock options	—	7,920
Net cash provided by financing activities	—	7,920
Effect of exchange rate changes on cash and cash equivalents	17,271	(16,808)
Net change in cash and cash equivalents	32,493,949	(52,925,461)
Cash and cash equivalents, beginning of year	18,505,493	71,430,954
Cash and cash equivalents, end of year	$ 50,999,442	$ 18,505,493
Supplemental disclosure of cash flow information:		
Right-of-use asset obtained in exchange for operating lease liability	$ 139,001	$ —
Income taxes paid	$ 3,667	$ —

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 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, substance dependence and addiction (e.g., methamphetamine dependence, opioid dependence, and alcohol

dependence), and prevention of acute respiratory distress syndrome (ARDS), and Long COVID, and MN-001 (tipelukast) for fibrotic and other diseases such as nonalcoholic fatty liver disease (NAFLD) and idiopathic pulmonary fibrosis (IPF). The Company's pipeline also includes MN-221 (bedoradrine) for the treatment of acute exacerbation of asthma, and MN-029 (denibulin) for solid tumor cancers.

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 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

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision-maker in making decisions regarding resource allocation and assessing performance. The Company operates in a single operating segment – the acquisition and development of small molecule therapeutics for the treatment of serious diseases with unmet medical needs.

Impact of COVID-19 on the Company's Business

The pandemic caused by an outbreak of a new strain of coronavirus ("COVID-19" or "the pandemic") has resulted, and is likely to continue to result, in significant national and global economic disruption and may adversely affect the Company's business. So far, the Company has experienced certain adverse effects on its business as well as been provided certain opportunities as a result of the pandemic. The pandemic caused a decrease in the number of patient visits at some clinical trial sites which the Company believes resulted in slower enrollment in the Company's clinical trials than would have occurred without the pandemic. However, the Company has seen an increase in the number of patient visits compared to earlier in the pandemic and the Company continues to enroll patients in clinical trials. Throughout the pandemic, the Company has continued with routine clinical trial activities including executing new clinical trial agreements, negotiating budgets, institutional review board (IRB) approvals, site training, and other activities related to the initiation of new clinical trials and the opening of new clinical trial sites, although some of these activities took longer to complete than what the Company experienced prior to the pandemic.

The pandemic created certain new opportunities for the Company's clinical development and the Company has pursued those opportunities. Following the outbreak of the pandemic, the Company designed a clinical trial to evaluate MN-166 (ibudilast) for prevention of acute respiratory distress syndrome (ARDS) caused by COVID-19. The Company continues to actively monitor the pandemic situation and the possible effects on its financial condition, liquidity, operations, suppliers, industry, and workforce.

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, 2023. As of December 31, 2022, investments consisted of bank certificates of deposit with original purchased maturity dates between seven and 13 months.

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 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 of an asset (or asset group) may not be recoverable, and the Company will perform an impairment analysis. Long-lived assets are deemed to be impaired when the undiscounted cash flows expected to be generated by the asset (or asset group) are less than the asset’s carrying amount. Any required impairment loss would be measured as the amount by which the asset’s (or asset group’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 of an asset (or asset group) 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 $8.7 5.3 million and $8.1 8.7 million for the years ended December 31, 2022 December 31, 2023 and 2021, 2022, 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, 2022 December 31, 2023 and 2022, respectively.

For transactions with a government where the Company receives government assistance in performing research and development activities and the accounting for a transaction is not specified within the scope of authoritative GAAP, the Company follows ASC 832, *Government Assistance (Topic 832)*, applying a grant or contribution model by analogy to Subtopic 958-605, *Not-for-Profit Entities-Revenue Recognition* ("ASC 958-605").

In 2021, respectively. the Company entered into an agreement with the Biomedical Advanced Research and Development Authority (BARDA), part of the Administration for Strategic Preparedness and Response (ASPR) at the U.S. Department of Health and Human Services, to develop MN-166 (ibudilast) as a potential medical countermeasure against chlorine gas-induced lung damage such as ARDS and acute lung injury (ALI). Under the agreement, BARDA agreed to provide federal funding for specified preclinical studies under Contract No. 75A50121C00022. The studies were completed in August 2023, and in September 2023, BARDA paid the Company $0.7 million to partially reimburse the costs of the studies. Contractual arrangements that are not considered an exchange of services are considered contributions under ASC 958-605, and the Company elected to recognize the $0.7 million in funding as an offset to research and development costs for the year ended December 31, 2023.

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, 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 amortized over the service period as the services are provided. As of December 31, 2023, the Company recorded $1.0 million and $0.0 million in clinical trial accruals and prepaid expenses, respectively. As of December 31, 2022, the Company recorded $1.5 million and $0.3 million in clinical trial accruals and prepaid expenses, respectively. As of December 31, 2021, the Company recorded $1.1 million and $0.4 million in clinical trial accruals and prepaid expenses, respectively.

Share-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 three to four 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.

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 7,985,250 7,781,749 and 7,974,250 7,985,250 consisting of stock options for the years ended December 31, 2022 December 31, 2023 and 2021, 2022, respectively, were excluded from diluted net loss per common share because of their anti-dilutive effect.

Recently Issued Accounting Pronouncements

In June 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-13, *Financial Instruments— Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* ("ASU 2016-13"). The ASU introduced a new credit loss methodology, the Current Expected Credit Losses ("CECL") methodology, which requires earlier recognition of credit losses, while also providing additional transparency about credit risk. The CECL methodology utilizes a lifetime "expected credit loss" measurement objective for the recognition of credit losses for loans, held-to maturity debt securities, trade receivables and other receivables measured at amortized cost at the time the financial asset is originated or acquired. Subsequent to the issuance of ASU 2016-13, the FASB issued several additional ASUs to clarify implementation guidance, provide narrow-scope improvements and provide additional disclosure guidance. In November 2019, the FASB issued an amendment making this ASU effective for fiscal years beginning after December 15, 2022 for smaller reporting companies. The new standard was effective for the Company on January 1, 2023. There was no impact on the consolidated financial statements upon adoption of this standard on January 1, 2023.

In August 2020, the FASB issued ASU No. 2020-06, *Debt – Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging – Contracts in Entity's Own Equity (Subtopic 815-40)* ("ASU 2020-06"). ASU 2020-06 simplifies the accounting for convertible debt instruments by reducing the number of accounting models and the number of embedded features that could be recognized separately from the host contract. Consequently, more convertible debt instruments will be accounted for as a single liability measured at its amortized cost, as long as no other features require bifurcation and recognition as derivatives. ASU 2020-06 also requires use of the if-converted method in the diluted earnings per share calculation for convertible instruments. ASU 2020-06 is effective for fiscal years beginning after December 15, 2023, and interim periods within those fiscal years for smaller reporting companies, with early adoption permitted. The new standard will be was effective for the Company on January 1, 2024. There was no impact on the consolidated financial statements upon adoption of this standard on January 1, 2024.

In October 2023, the FASB issued ASU 2023-06, *Disclosure Improvements: Codification Amendments in Response to the SEC's Disclosure Update and Simplification Initiative*. ASU 2023-06 modifies the disclosure or at presentation requirements of a variety of Topics in the Codification. Specifically, the amendments align the

requirements in the Codification with the SEC's regulations. The amendments apply to all reporting entities within the scope of the affected Topics unless otherwise indicated. For entities subject to the SEC's existing disclosure requirements and for entities required to file or furnish financial statements with or to the SEC, the effective date for each amendment will be the date on which the SEC's removal of that related disclosure requirement from Regulation S-X or Regulation S-K becomes effective, with early adoption prohibited. For all other entities, the amendments will be effective two years after the date of such earlier time where it is no longer a smaller reporting company. removal. The amendments should be applied prospectively. The Company is currently evaluating the potential impact that this standard will have on its consolidated financial statements and related disclosures.

In November 2023, the FASB issued ASU 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*. ASU 2023-07 improves the disclosures about a public entity's reportable segments and addresses requests from investors for additional, more detailed information about a reportable segment's expenses. Specifically, it requires that a public entity: 1) disclose, on an annual and interim basis, significant segment expenses that are regularly provided to the chief operating decision maker (CODM) and included within each reported measure of segment profit or loss, 2) disclose, on an annual and interim basis, an amount for other segment items by reportable segment and a description of its composition. The other segment items category is the difference between segment revenue less the segment expenses disclosed under the significant expense principle and each reported measure of segment profit or loss, 3) provide all annual disclosures about a reportable segment's profit or loss and assets currently required by Topic 280 in interim periods, and 4) disclose the title and position of the CODM and an explanation of how the CODM uses the reported measure(s) of segment profit or loss in assessing segment performance and deciding how to allocate resources. The ASU also requires a public entity that has a single reportable segment to provide all the disclosures required by the amendments in this ASU and all existing segment disclosures in Topic 280. Further, the ASU clarifies that if the CODM uses more than one measure of a segment's profit or loss in assessing segment performance and deciding how to allocate resources, a public entity may report one or more of those additional measures. However, at least one of the reported segment profit or loss measures should be the measure that is most consistent with the measurement principles used in measuring the corresponding amounts in the public entity's consolidated financial statements. The amendments are effective for all public

entities that are required to report segment information for fiscal years beginning after December 15, 2023 and interim periods beginning after December 15, 2024. Early adoption is permitted. The amendments should be applied retrospectively to all prior periods presented. The Company is currently evaluating the potential impact that this standard will have on its consolidated financial statements and related disclosures.

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 is currently evaluating the potential impact that this standard will have on its consolidated financial statements and related disclosures.

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2. Revenue Recognition

Revenue Recognition Policy

Revenues historically have consisted mainly of research and development services performed under a contract with a customer. The Company evaluates the separate performance obligation(s) under each contract, allocates the

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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.

Kissei Pharmaceutical Co., Ltd

In October 2011, the Company entered into a collaboration agreement with Kissei Pharmaceutical Co., Ltd., ("Kissei"), to perform research and development services relating to MN-221 (bedoradrine) in exchange for a non-refundable upfront payment of $2.5 million. The Company assessed the services in accordance with the authoritative guidance and concluded that its met the definition of a collaborative arrangement per Accounting Standards Codification (ASC) 808, *Collaborative Arrangements* ("ASC 808") which is outside of the scope of ASC 606, *Revenue from Contracts with Customers*("ASC 606"). Since ASC 808 did not provide recognition and measurement guidance for collaborative arrangements, the Company analogized to ASC 606 and concluded that the two studies to be performed under the agreement represented two separate performance obligations. No services have been provided and no revenue has been recognized under the collaboration agreement subsequent to completion of the first study in 2013. In October 2021, the Company refunded $1.3 million of the prepayment. As of December 31, 2021, the Company and Kissei were working to mutually terminate the collaboration agreement and on October 24, 2022, the Company and Kissei finalized the termination of the collaboration agreement and canceled the second study contemplated thereunder. The Company has no further financial obligations to Kissei.

Genzyme Corporation

In December 2005, Avigen, Inc. and Genzyme Corporation ("Genzyme") entered into an Assignment Agreement (the "Genzyme Agreement") in which Genzyme acquired certain gene therapy intellectual property, programs and other related assets from Avigen, Inc. in exchange for an initial $12 million payment. Avigen could also receive upfront payment and potential additional development milestone payments, sublicensing fees, and royalty payments based on the successful development of products by Genzyme utilizing technologies previously developed by Avigen. The Company subsequently acquired Avigen in December 2009 along with Avigen's rights and obligations under the Genzyme Agreement. If Genzyme fails to diligently pursue the commercialization or marketing of products using the assigned technology, as specified in the Genzyme Agreement, some of the rights assigned could revert back to the Company at a future date.

The development milestones outlined in the Genzyme Agreement did not meet the definition of a substantive milestone obligation under authoritative guidance on revenue recognition for milestone payments, as Genzyme was responsible for the development of the product and there is no further substantive service effort required by the Company. In March 2021, September 2023, the Company received notice that a gene therapy product based on AAV (adeno-associated virus) vector technology, which was covered under the Genzyme Agreement, achieved two one clinical development milestones, milestone, triggering two a milestone payments. payment of $1.0 million. Accordingly, the Company recognized revenue of $4.0 1.0 million for the year ended December 31, 2021 December 31, 2023.

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, 2022 December 31, 2023 and 2021, 2022, were as follows:

	December 31, 2022		December 31, 2021			December 31, 2023		December 31, 2022		
	Carrying Amount	Fair Value	Carrying Amount	Fair Value	Valuation Inputs	Carrying Amount	Fair Value	Carrying Amount	Fair Value	Valuation Inputs
Cash equivalents:										
Money market funds	704,882	$ 704,882	694,296	$ 694,296	Level 1					
Mutual funds						$ 782,382	$ 782,382	$ 704,882	$ 704,882	Level 1

Investments:										
Bank certificates of deposit	$ 39,982,213	$ 39,982,213	—	—	Level 2		—	—	39,982,213	39,982,213	Level 2

Short-term investments consisting of bank certificates of deposit with an original purchased maturity greater than three months are classified as held-to-maturity and are stated at amortized cost, which approximates fair value due to the short-term maturities and market rates of interest of these instruments.

4. Balance Sheet Details

Property and Equipment

Property and equipment, net, consist of the following:

	December 31,		December 31,	
	2022	2021	2023	2022
Leasehold improvements	$ 13,532	$ 15,409	$ 12,579	$ 13,532
Furniture and equipment	121,909	124,731	134,106	121,909
Software	342,628	342,628	342,628	342,628
	478,069	482,768	489,313	478,069
Less accumulated depreciation and amortization	(432,800)	(425,203)	(443,513)	(432,800)
Property and equipment, net	$ 45,269	$ 57,565	$ 45,800	$ 45,269

The Company uses the straight-line method to record depreciation expense with useful lives of three to five years. Leasehold improvements are amortized over a useful life of five years. Depreciation and amortization of property and

equipment of $17,707 20,295 and $26,149 17,707 was recorded for the years ended December 31, 2022 December 31, 2023 and 2021, 2022, respectively.

Accrued Liabilities and Other Current Liabilities

Accrued liabilities and other current liabilities consist of the following:

	December 31,		December 31,	
	2022	2021	2023	2022
Accrued compensation	$ 920,166	$ 636,481	$ 824,390	$ 920,166
	1,462,35	1,076,41		
Clinical trial accruals	4	1	1,034,720	1,462,354
Professional services fees	38,688	38,041	35,753	38,688
Other	184,100	547,270	164,375	184,100
Total accrued liabilities and other current liabilities	2,605,30 8	2,298,20 3	$ 2,059,238	$ 2,605,308

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. The Company's lease in Tokyo, Japan has a term of two years ending May 2023 2025 with an auto-renewal, two-year extension. In June 2023, the Company renewed the Japan lease. The auto-renewal was not included in the measurement of the lease liability as renewal at the end of the lease term was not reasonably certain. The real estate operating leases are included in "Right-of-use asset" on the Company's balance sheet 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 sheet.sheets.

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

	Year Ended December 31,		Year Ended December 31,	
	2022	2021	2023	2022
Cash paid for operating lease liabilities	$ 198,035	$ 242,676	$ 257,326	$ 198,035
Operating lease costs	248,610	228,779	257,931	248,610
Right-of-use assets obtained in exchange for new operating lease obligations	—	870,373	139,001	—
Current operating lease liabilities	$ 157,505	$ 131,965	$ 215,926	$ 157,505
Non-current operating lease liabilities	523,619	694,674	410,660	523,619
Total operating lease liabilities	$ 681,124	$ 826,639	$ 626,586	$ 681,124
Weighted-average remaining lease term	3.90	4.54	2.81	3.90
Weighted-average discount rate	9.8%	9.8%	9.3%	9.8%

Maturities of operating lease liabilities as of December 31, 2022 were as follows:		
2023	$ 216,154	
Maturities of operating lease liabilities as of December 31, 2023 were as follows:		
2024	189,170	$ 265,698
2025	197,585	229,472
2026	206,483	206,483
2027	17,269	17,269
2028		—
Thereafter	-	—
Total minimum payments	$ 826,661	$ 718,922
Less imputed interest	(145,537)	(92,336)
Total lease liabilities	$ 681,124	$ 626,586

Product Liability

The Company's business exposes it to liability risks from its potential drug products. A successful product liability claim or series of claims brought against the Company could result in the payment of significant amounts of money and divert management's attention from running the business. The Company may not be able to maintain insurance on acceptable terms, or the insurance may not provide adequate protection in the case of a product liability claim. To the extent that product liability insurance, if available, does not cover potential claims, the Company would be required to self-insure the risks associated with such claims. The Company believes it carries reasonably adequate insurance for product liability.

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, 2022 December 31, 2023 and 2021. 2022. 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, 2022 December 31, 2023. For all other products, future potential milestone payments related to development milestones and commercialization milestones totaled $16.5 million as of December 31, 2022 December 31, 2023. 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"), 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 2013 2023 Plan is the successor to the Company’s Amended and Restated 2004 Stock Incentive Plan, or 2004 2013 Plan. A total The number of8,700,000 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. 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 addition, “returning shares” general, to the extent that may 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 from time to time for issuance under the 2023 Plan. If stock appreciation rights are added back exercised or restricted stock units are settled, then only the number of shares (if any) actually issued to the plan. Returning participant will reduce the number of shares are shares that are subject to outstanding awards granted available under the 2004 Plan that expire 2023 Plan. If restricted shares or terminate prior shares issued upon exercise of options are reacquired by the Company pursuant to exercise a forfeiture provision, repurchase right or settlement, are forfeited because of for any other reason, then such shares shall again become available for issuance under the failure to vest, are repurchased, or are 2023 Plan. Shares

withheld to pay the exercise price of options or satisfy tax withholding or purchase price obligations in connection with such awards. Although the Company no longer grants equity awards related to an award shall again become available for issuance under the 2004 Plan, all outstanding stock awards granted 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 2004 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 2004 2023 Plan.

As of December 31, 2022 December 31, 2023, 1,949,317 2,152,818 shares remain available for future grant under the 2013 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

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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, 2022 December 31, 2023, there were a total of 533,700 730,350 shares underlying performance options that were

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subject to vesting based on achievement of corporate objectives for 2022. 2023. In January 2023, 2024, the compensation committee and the board of directors determined that the performance milestones were achieved at the 95 70% level and accordingly 507,015 511,245 of these options vested and the remaining shares were forfeited.

Stock Options

Options granted under the 2013 2023 Plan and 2004 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, 2022 December 31, 2023 and 2021 2022 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, 2022 December 31, 2023 and 2021 2022 is as follows:

	Number of Option Shares	Weighted Average Exercise Price	Number of Option Shares	Weighted Average Exercise Price
Outstanding at December 31, 2020	7,401,387	$ 5.70		
Granted	1,315,000	$ 5.82		
Exercised	(360,955)	$ 2.47		
Cancelled	(381,182)	$ 6.77		
Outstanding at December 31, 2021	7,974,250	$ 5.81	7,974,250	$ 5.81
Granted	591,700	$ 2.28	591,700	$ 2.28
Exercised	(3,000)	$ 2.64	(3,000)	$ 2.64
Cancelled	(577,700)	$ 5.85	(577,700)	$ 5.85
Outstanding at December 31, 2022	7,985,250	$ 5.55	7,985,250	$ 5.55
Exercisable at December 31, 2022	7,394,381	$ 5.80		
Granted			788,683	$ 2.39
Exercised			—	$ -
Cancelled			(992,184)	$ 3.27
Outstanding at December 31, 2023			7,781,749	$ 5.52
Exercisable at December 31, 2023			7,008,232	$ 5.86

Number of Option Shares	Weighted Average Grant-Date Fair Value	Number of Option Shares	Weighted Average Grant-Date Fair Value

Non-vested at December 31, 2021	1,286,33	$	3.54			
Non-vested at December 31, 2022				590,869	$	1.52
Granted	591,700	$	1.47	788,683	$	1.59
Vested	(738,134)	$	3.47	(579,351)	$	1.51
Forfeitures	(549,030)	$	3.58	(26,684)	$	1.45
Non-vested at December 31, 2022	590,869	$	1.52			
Non-vested at December 31, 2023				773,517	$	1.61

The aggregate intrinsic value of options exercised was $1,410 0 and $0.7 1,410 million for the years ended December 31, 2022 December 31, 2023 and 2021, 2022, respectively. Options outstanding and exercisable at December 31, 2022 December 31, 2023 had a weighted average contractual life of 4.89 4.47 years and 4.56 4.89 years, respectively.

As of December 31, 2022 December 31, 2023 and 2021, 2022, the total intrinsic value of options outstanding was $0 and $32,840 0, respectively. Total intrinsic value of options exercisable was $0 and $32,840 0 as of December 31, 2022 December 31, 2023 and 2021, 2022, respectively. Total fair value of options vested was $2.6 0.9 million and $4.2 2.6 million for the years ended December 31, 2022 December 31, 2023 and 2021, 2022, respectively.

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Employee Stock Purchase Plan

Under the Company's 2007 Employee Stock Purchase Plan (ESPP), 300,000 shares of common stock were originally reserved for issuance. In addition, the shares reserved automatically increase each year by a number equal to the lesser of: (i) 15,000 shares; (ii) 1% of the outstanding shares of common stock on the last day of the immediately preceding fiscal year; or (iii) such amount as determined by the Board. The ESPP permits full-time employees to purchase common stock through payroll deductions (which cannot exceed 15% of each employee's compensation) at the lower of 85% of fair market

value at the beginning of the offering period or the end of each six-month offering period. The ESPP is considered a compensatory plan and the Company records compensation expense.

For the year ended December 31, 2021 an aggregate of 1,424 shares were issued under the ESPP. No further shares will be issued under the ESPP.

Compensation Expense

The estimated fair value of each stock option award was determined on the date of grant using the Black-Scholes option valuation model with the following weighted-average assumptions for stock option grants:

	Year Ended December 31,		Year Ended December 31,	
	2022	2021	2023	2022
Stock Options				
Risk-free interest rate	3.88%	0.58%	3.83%	3.88%
Expected volatility of common stock	78.81%	72.41%	75.28%	78.81%
Dividend yield	0.00%	0.00%	0.00%	0.00%
Expected option term (in years)	4.70	5.48	4.68	4.70

The estimated fair value of employee stock purchase rights under the Company's ESPP was determined on the date of grant using the Black-Scholes option valuation model with the following weighted-average assumptions:

	Year Ended December 31,	
	2022	2021
Employee Stock Purchase Plan		
Risk-free interest rate	—	0.05%
Expected volatility of common stock	—	83.40%
Dividend yield	—	0.00%
Expected option term (in years)	—	0.5

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, 2022 December 31, 2023 and 2021, 2022, estimated as of the grant date using the Black-Scholes option valuation model, was $1.47 1.59 per option and $3.51 1.47 per option, respectively.

Stock-based compensation expense for stock option awards and ESPP shares are reflected in total operating expenses for each respective year.

The following table summarizes stock-based compensation expense for the years ended December 31, 2022 December 31, 2023 and 2021: 2022:

	December 31,		December 31,	
	2022	2021	2023	2022
Research, development and patents	$ 237,071	$ 640,340	$ 240,268	$ 237,071
General and administrative	405,451	1,077,173	470,442	405,451
Total stock-based compensation expense	$ 642,522	$ 1,717,513	$ 710,710	$ 642,522

As of December 31, 2022 December 31, 2023, there was $0.2 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 0.20 0.06 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) pursuant to which the Company may sell common stock through B. Riley FBR from time to time up to an aggregate offering price of $75.0 million. Sales of the Company's common stock through B. Riley FBR, 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. B. Riley FBR may also sell the common stock in privately negotiated transactions, subject to the Company's prior approval. The Company agreed to pay B. Riley FBR an aggregate commission rate of up to 3.5% 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 B. Riley FBR and the per share purchase price of each transaction.

No shares of common stock were sold under the ATM Agreement in the years ended December 31, 2022 December 31, 2023 and 2021, 2022, respectively.

Private Placement Transactions

On January 29, 2021, the Company sold and issued to an investor 3,656,307 shares of the Company's common stock at a price of $5.47 per share for approximately $20 million in cash proceeds, net of approximately $0.1 million in issuance costs, in a private placement pursuant to the terms and conditions of a Securities Purchase Agreement dated as of January 11, 2021 by and between the Company and such investor.

Common Stock Reserved for Future Issuance

The following table summarizes common stock reserved for future issuance at December 31, 2022 December 31, 2023:

Common stock reserved for issuance upon exercise of options outstanding (under the 2004 Plan, and 2013 Plan 2013 and 2023 Plan)	7,985,250 7,781,749
Common stock reserved for future equity awards (under the 2013 2023 Plan)	1,949,317 2,152,818
	9,934,567

8. Income Taxes

A reconciliation of loss before income taxes for domestic and foreign locations for the years ended December 31, 2022 December 31, 2023 and 2021 2022 is as follows:

	Year Ended December 31,	
	2022	2021
United States	$ (14,084,240)	$ (10,145,822)
Foreign	17,979	14,138
Loss before income taxes	$ (14,066,261)	$ (10,131,684)

	Year Ended December 31,	
	2023	2022
United States	$ (8,587,967)	$ (14,084,240)
Foreign	19,498	17,979
Loss before income taxes	$ (8,568,469)	$ (14,066,261)

A reconciliation of income tax expense for the years ended December 31, 2022 December 31, 2023 and 2021 2022 is as follows:

	Year Ended December 31,		Year Ended December 31,	
Current:	2022	2021	2023	2022
Federal	$ —	$ —	$ —	$ —
State	—	—	—	—
Foreign	(2,822)	(2,568)	(3,047)	(2,822)
Total current income tax expense	(2,822)	(2,568)	(3,047)	(2,822)
Deferred:				
Federal	—	—	—	—
State	—	—	—	—
Foreign	—	—	—	—
Total deferred income tax expense	—	—	—	—
Total income tax expense	$ (2,822)	$ (2,568)	$ (3,047)	$ (2,822)

The significant components of deferred income taxes at December 31, 2022 December 31, 2023 and 2021 2022 are as follows:

	Year Ended December 31,	
Deferred tax assets:	2022	2021
Net operating loss carryforwards	$ 70,142,367	$ 68,485,037
Capitalized licenses	934	30,784
Research tax credits	9,629,956	9,262,071
Stock options	1,526,644	1,601,862

Other, net	390,610	423,279
Right-of-use asset	180,938	196,059
Research and experimentation capitalization	1,795,580	—
Total deferred tax assets	83,667,029	79,999,092
Deferred tax liabilities		
Right-of-use liability	(166,786)	(196,059)
In-process research and development	(1,343,213)	(1,343,213)
Total deferred tax liabilities	(1,509,999)	(1,539,272)
Net deferred tax assets	82,157,030	78,459,820
Valuation allowance	(82,358,822)	(78,661,612)
Net deferred tax liability	$ (201,792)	$ (201,792)

	Year Ended December 31,	
Deferred tax assets:	**2023**	**2022**
Net operating loss carryforwards	$ 69,980,468	$ 70,142,367
Capitalized licenses	—	934
Research tax credits	10,034,233	9,629,956
Stock options	1,497,450	1,526,644
Other, net	355,204	390,610
Right-of-use asset	166,832	180,938
Research and experimentation capitalization	2,626,585	1,795,580
Total deferred tax assets	84,660,772	83,667,029
Deferred tax liabilities		
Right-of-use liability	(152,511)	(166,786)
In-process research and development	(1,343,213)	(1,343,213)
Total deferred tax liabilities	(1,495,724)	(1,509,999)
Net deferred tax assets	83,165,048	82,157,030
Valuation allowance	(83,366,840)	(82,358,822)
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, 2022 December 31, 2023 was an increase of $3.7 1.0 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.

At December 31, 2022 December 31, 2023, the Company has federal and California net operating loss (NOL) carryforwards of approximately $276.6 275.9 million and $182.9 190.5 million, respectively. $232.3 227.4 million of federal NOL carryforwards began begin to expire in 2022 2024, $44.3 48.5 million of federal NOL carryforwards can be carried forward indefinitely, and the California NOL carryforwards begin to expire in 2028. At December 31, 2022 December 31, 2023, the Company also had federal and California research tax credit carry-forwards of approximately $7.8 8.2 million and $2.3 2.4 million, respectively. The federal research tax credit carryforwards will begin to expire in 2024, 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 has not completed an IRC Section 382/383 analysis since 2011 regarding the limitation of net operating loss and research and development credit carryforwards. carryforwards for a period of inception through December 2022, 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, which was through December 2011. 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.

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

Year Ended December 31,		Year Ended December 31,	
2022	2021	2023	2022

Federal statutory income tax rate	21.0%	21.0%	21.0%	21.0%
State income taxes, net of federal benefit	6.4	2.7	6.3	6.4
Tax credits	2.6	2.8	3.8	2.6
Change in valuation allowance	(26.4)	3.5	(11.8)	(26.4)
Permanent differences	(0.3)	(0.2)	—	(0.3)
Expiration of attributes	(1.3)	(10.4)	(12.0)	(1.3)
Stock compensation	(1.9)	(12.4)	(1.9)	(1.9)
Uncertain tax positions	—	(7.0)	(6.4)	—
Other	(0.1)	—	1.0	(0.1)
Provision for income taxes	0.0%	0.0%	0.0%	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,	
	2022	2021
Gross unrecognized tax benefits at January 1	$ 893,371	$ -
Additions for tax positions taken in the prior year	3,610	-
Additions for tax positions taken in the current year	-	893,371
Gross unrecognized tax benefits at December 31	$ 896,981	$ 893,371

	Year Ended December 31,	
	2023	2022
Gross unrecognized tax benefits at January 1	$ 896,981	$ 893,371
Additions for tax positions taken in the prior year	—	3,610
Additions for tax positions taken in the current year	692,285	—
Gross unrecognized tax benefits at December 31	$ 1,589,266	$ 896,981

If recognized, none of the unrecognized tax benefits as of December 31, 2022 December 31, 2023 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 essentially subject to income tax examination by tax authorities from inception to date. The Company's policy is to recognize interest expense and penalties related to income tax matters as tax expense. At December 31, 2022 December 31, 2023, 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 $75,859 115,950 and $72,330 75,859 for the years ended December 31, 2022 December 31, 2023 and 2021, 2022, 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, 2022 December 31, 2023, 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 statemen 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 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, 2022 December 31, 2023.

Item 9B. Other Information

On October 24, 2022, we terminated our exclusive license agreement, dated February 25, 2004 (Kissei License Agreement), with Kissei Pharmaceutical Co., Ltd. (Kissei) pursuant to a comprehensive termination agreement with Kissei (Termination Agreement). Under the Termination Agreement we had no further financial obligations to Kissei other than the purchase of 7.15kg of active pharmaceutical ingredient already manufactured by Kissei pursuant to the Kissei License Agreement for an aggregate purchase price of JPY114,400,000, which we purchased in December 2022. (a) None.

(b)

The foregoing summary Securities Trading Plans of Directors and Executive Officers

During the last fiscal quarter of the Termination Agreement is not complete and is subject to, qualified year ended December 31, 2023, none of our officers or directors, as defined in its entirety by, and should be read in conjunction with, the full text Rule 16a-1(f), informed us of the Termination Agreement, which is filedadoption or termination of a Rule 10b5-1 trading arrangement or a non-Rule 10b5-1 trading arrangement, each as Exhibit 10.27 to this Annual Report on Form 10-K. 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 the sections titled “Election of Directors,” “Section 16(a) Beneficial Ownership Reporting Compliance”, “Corporate Governance,” “Meetings and Committees of the Board”, and “Executive Officers” in our definitive proxy statement for our 2023 2024 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the conclusion of our fiscal year ended December 31, 2022 December 31, 2023 (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.

Item 11. Executive Compensation

The information required by this item will be contained in the section titled “Executive Compensation” 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 the section titled “Security Ownership of Certain Beneficial Owners and Management” 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, 2022 December 31, 2023 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	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)	7,985,250	$ 5.55	1,949,317	7,781,749	$ 5.52	2,152,818
Equity Compensation Plans not approved by security holders	—	—	—	—	—	—
Total	7,985,250	$ 5.55	1,949,317	7,781,749	$ 5.52	2,152,818

(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). Under the ESPP, the shares reserved automatically increase by a number equal to the lesser of: (i) 15,000 shares; (ii) 1% of the outstanding shares of our common stock on t last day of the immediately preceding fiscal year; or (iii) an amount determined by the Board.

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

The information required by this item will be contained in the sections titled “Certain Relationships and Related Transactions” and “Corporate Governance” 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 the section titled “Ratification of Appointment of Independent Registered Public Accounting Firm” 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, LLP, 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, by and 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*	Amended and Restated 2004 Stock Incentive Plan of the Registrant (incorporated by reference to Exhibit 10.2 of the Registrant's Annual Report on Form 10-K (File No. 001-33185) filed March 29, 2012).
10.2*	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).
10.3†	License Agreement, dated March 14, 2002, between the Registrant and Kyorin Pharmaceutical Co., Ltd. (incorporated by reference to Exhibit 10.4 of the Registrant's Registration Statement on Form S-1, S-1/A, as amended (File No. 333-119433), originally filed on October 1, 2004 November 24, 2004).
10.4†	License Agreement, dated June 19, 2002, between the Registrant and Angiogene Pharmaceuticals, Ltd. (incorporated by reference to Exhibit 10.5 of the Registrant's Registration Statement on Form S-1, S-1/A, as amended (File No. 333-119433), originally filed on October 1, 2004 November 24, 2004).

10.5†	Exclusive License Agreement, dated February 25, 2004, between the Registrant and Kissei Pharmaceutical Co., Ltd. (incorporated by reference to Exhibit 10.7 of the Registrant's Registration Statement on Form S-1, S-1/A, as amended (File No. 333-119433), originally filed on October 1, 2004 November 24, 2004).
10.6†	License Agreement, dated October 22, 2004, between the Registrant and Kyorin Pharmaceutical Co., Ltd., (incorporated by reference to Exhibit 10.18 of the Registrant's Registration Statement on Form S-1, S-1/A, as amended (File No. 333-119433), originally filed on October 1, 2004 November 24, 2004).

Exhibit Number	Description
10.7†	License Agreement, dated October 31, 2006, by and between the Registrant and Meiji Seika Kaisha, Ltd. (incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K (File No. 000-51133) filed November 2, 2006).
10.8†	License Agreement, dated October 31, 2006, by and between the Registrant and Meiji Seika Kaisha, Ltd. (incorporated by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K (File No. 000-51133) filed November 2, 2006).
10.9*	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).
10.10*	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).
10.11†	Development and Supply Agreement, dated as of March 26, 2009, between the Registrant and Hospira Worldwide, Inc. (incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K (File No. 001-33185) filed March 30, 2009).

10.12†	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. 000-51133) 000-28272) filed February 16, 2006 March 16, 2006).
10.13†	Asset Purchase Agreement, dated December 17, 2008, between Baxter Healthcare Corporation, Baxter International Inc., and Baxter Healthcare S.A. and Avigen, Inc. (incorporated by reference to Exhibit 2.2 of Avigen, Inc.'s Annual Report on Form 10-K (File No. 001-33185) 000-28272-) filed March 31, 2009 March 16, 2009).
10.14*	Form of First Amendment to Employment Agreement, dated December 31, 2011 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).
10.15	Sublease, by and between MediciNova, Inc. the Registrant and Cardinal Health 127 Inc., dated August 31, 2017 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-33185) filed with the SEC on September 7, 2017).
10.16*	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).
10.17*	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).
10.18*	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).
10.19*	Severance Protection Agreement, dated July 14, 2014, by and between MediciNova, Inc. 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).
10.20*	Severance Protection Agreement, dated July 14, 2014, by and between MediciNova, Inc. 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).

10.21*	Severance Protection Agreement, dated July 14, 2014, by and between MediciNova, Inc. 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).
10.22	At Market Issuance Sales Agreement, dated August 23, 2019, by and between MediciNova, Inc. and B. Riley FBR, Inc. (incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K (File No. 001-33185) filed August 23, 2019).
10.23	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.).

Exhibit Number	Description
10.24	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.).
10.25	Services Agreement, dated August 1, 2021, by and between MediciNova, Inc. and Signature Analytics LLC (incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K (File No. 001-33185) filed August 2, 2021.).
10.26	Lease, dated July 20, 2021, by and 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.).

10.27	Comprehensive Termination Agreement, dated October 24, 2022, by and between Medicinova, Inc. the Registrant and Kissei Pharmaceutical Co., Ltd. (incorporated by reference to Exhibit 10.27 of the Registrant's Annual Report on Form 10-K/A (File No. 001-33185) filed March 28, 2023).
10.28*	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).
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.
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.
101	The following financial statements from MediciNova, Inc. on Form 10-K as of and for the year ended December 31, 2022 December 31, 2023 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: February 16, 2023 February 15, 2024

By: /s/ Yuichi Iwaki

Yuichi Iwaki, M.D., Ph.D.

President & Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL MEN 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.	Director, Chairman of the Board of Directors, President and Chief Executive Officer *(Principal executive officer)*	February 16, 2023 15, 2024
/s/ Jason Kruger Jason Kruger	Chief Financial Officer *(Principal financial and accounting officer)*	February 16, 2023
/s/ Jeff Himawan Jeff Himawan, Ph.D.	Chairman of the Board of Directors	February 16, 2023 15, 2024
/s/ Carolyn Beaver Carolyn Beaver	Director	February 16, 2023 15, 2024
/s/ Kazuko Matsuda Nicole Lemerond Kazuko Matsuda Nicole Lemerond	Director	February 16, 2023 15, 2024
/s/ Kazuko Matsuda Kazuko Matsuda	Director	February 15, 2024
/s/ Hideki Nagao Hideki Nagao	Director	February 16, 2023 15, 2024

Exhibit 10.27 19.1

MEDICINOVA, INC.

Statement of Company Policy

COMPREHENSIVE TERMINATION AGREEMENT

This Comprehensive Termination Agreement (the "Agreement") is made as of this 24th day of October, 2022 (the "Effective Date") Trades in the Company's Securities by Insiders (Company Personnel, Board Members and between Kissei Pharmaceutical Co., Ltd., a corporation duly organized designated Consultants, Advisors and existing under Contractors to the laws of Japan Company) and having its registered office at 19-48, Yoshino, Matsumoto-City, Nagano-Prefecture 399-8710, Japan ("Kissei") and MediciNova, Inc., a corporation duly organized and existing under the laws of the State of Delaware, United States and having its registered office at 4350 La Jolla Village Dr., Ste. 950, San Diego, California 92122, USA ("MediciNova"). Each of Kissei and MediciNova is referred to herein as a "Party" and collectively, as the "Parties." Confidential Information

1. Purpose.

Termination. Both the Securities and Exchange Commission (the **"SEC"**) and Congress are concerned about maintaining the fairness of the U.S. securities markets, and the SEC, together with the U.S. Attorney's Office, pursues insider trading violations vigorously. Cases have been prosecuted successfully against trading by employees through foreign accounts, trading by family members and friends and trading involving only a small number of shares.

Federal and state securities laws prohibit the purchase or sale of a company's securities by persons who are aware of material information that is not generally known or available to the public. These laws prohibit persons who are aware of such material non-public information from disclosing it to others who may trade. The securities laws require publicly-traded companies to take reasonable steps to prevent insider trading by company personnel. Companies and their controlling persons are subject to liability if they fail to take reasonable steps to prevent insider trading by company personnel.

This Statement of Company Policy ("**Policy**") is designed to prevent insider trading or allegations of insider trading and to protect the Company's reputation for integrity and ethical conduct. This Policy applies to all employees of MediciNova, Inc. (the **"Company"**), all members of the Board of Directors of the Company (the "**Board of Directors**") and designated consultants, advisors and contractors to the Company, and they are obligated to understand and comply with this Policy. References to "you" (as well as general references to directors, officers, employees, consultants, advisors and contractors of the Company) should also be understood to include members of your immediate family, persons with whom you share a household, persons who are your economic dependents and any other individuals or entities whose transactions in securities you direct, control (including, for example, a trust or a venture or other investment fund, if you direct or control transactions for the entity).

Individuals affecting transactions in Japan also need to abide by the laws set out in the Financial Instruments and Exchange Law (the **"FIEL"**) and the rules and regulations set out in the Rules of the Japanese Securities Market.

The Company has appointed the CFO, or his or her designee, as its current Insider Trading Compliance Officer ("**COMPLIANCE OFFICER**"). Please direct your questions as to any matters discussed

in this Policy to the **COMPLIANCE OFFICER**.

2. The Consequences.

The consequences of insider trading violations can be substantial, with civil and criminal penalties potentially including,

Insider trading violations by individuals:

- Damages in a private lawsuit;

- Disgorging any profits made or losses avoided;
- Imprisonment of up to twenty years; A bar against serving as an officer or director of a public company;

(a) •A civil penalty of up to three times the profit gained or loss avoided;

- An injunction against future violations; and
- A criminal fine of up to $5 million.
- Under Japanese law there is a penalty of up to five years in prison and a fine of up to JPY 5 million.

Liabilities if the Company fails to take appropriate steps to prevent insider trading. (Further, civil penalties can extend personal liability to the Company's directors, officers and other supervisory personnel as "controlling persons".):

- A civil penalty of the greater of $2.479 million or three times the profit gained or loss avoided; and
- A criminal penalty of up to $25 million.
- Under Japanese law there is a maximum fine of JPY 300 million.

Company-imposed sanctions, including dismissal for cause, could result if an individual violates the insider trading policy, whether or not this individual's actions also violate the law. It is not necessary for the Company to wait for the filing or conclusion of any civil or criminal action against you before taking disciplinary action. In addition, Company may give stop transfer and other instructions to Company's transfer agent to enforce compliance with this Policy.

3. Policy.

Except as provided in the section titled "**Limited Exceptions**" below, **you may not, directly or indirectly through others, engage in any transaction involving the Company's securities while**

aware of material non-public information. If you have material non-public information (often referred to as "**insider information**") relating to the Company, it is our policy that neither you nor any related person may buy or sell securities of the Company or engage in any other action to take advantage of, or pass on to others, that information. Even the appearance of an improper transaction must be avoided to prevent possible insider information violations and to preserve our reputation for adhering to the highest standards of conduct.

Similarly, this policy also applies to trading in the securities of any other company if you became aware of material non-public information about that company in the course of your relationship with the Company (except if the transactions are similar to those presented in the section titled "**Limited Exceptions**" below). For example, you may be aware of a proposed transaction involving a prospective business relationship or transaction with another company. If information about that transaction constitutes material non-public information for that other company, you would be prohibited from engaging in transactions involving the securities of that other company (as well as transactions involving the Company's securities, if that information is material to the Company). "**Materiality**" is company-specific — information that is not material to the Company may be material to another company.

Material information is any information that a reasonable investor would consider important in deciding whether to buy, hold or sell securities of the Company. Material information includes any information that reasonably could affect the price of the stock. Either positive or negative information may be material and material information may be about the Company or about a company with which

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we do business.

Examples: Common examples of information that will frequently be regarded as material are:

- financial results, financial condition, earnings pre-announcements, guidance projections or forecast (note that information about the results of the Company's operations for even a portion of a quarter might be material in helping predict the Company's financial results for the quarter);
- news of a possible merger, acquisition or tender offer;
- news of a significant sale of assets;
- significant new products or delays in new product introduction or development;
- discoveries, or grants or allowances or disallowances of patents;
- changes in dividend policies or the declaration of a stock split or the offering of additional securities;
- changes in management;

- changes in independent auditors, or notification that the Company may no longer rely on an audit report;
- restatements of financial results, or material impairments, write-offs or restructurings;
- significant legal or regulatory developments, whether actual or threatened;
- a significant cybersecurity incident, such as a data breach, or any other significant disruption, loss, breach or unauthorized access of the Company's property or assets, whether at the Company's facilities or through the Company's technology infrastructure;
- plans to raise additional capital through stock sales or otherwise;
- the gain or loss of a significant product sale, customer or collaborator;
- impending bankruptcy or financial liquidity problems; and
- the gain or loss of a substantial customer or supplier.

The Parties herby agree FIEL lists specific events that are considered to forthwith terminate be "material inside information" and also contains a catch all provision for events not specifically mentioned in the Exclusive License Agreement (the "License Agreement") law. A non-exhaustive list of facts which could be material information under the FIEL is attached as Exhibit D to this Statement of Company Policy.

Hindsight. Securities transactions that become the subject of scrutiny will be viewed after-the-fact with the benefit of hindsight. As a result, before engaging in any transaction, you should carefully consider how others might view your transaction in hindsight.

Transactions by Family Members. The same restrictions apply to your family members and others living in your household as apply to you. You are responsible for the compliance to this Policy by your immediate family and personal household members.

Do Not Pass Information to Others. Whether the information is proprietary information about the Company or information that could have an impact on our stock price, you must not pass the information on to others. You may not advise others to trade on the basis of material non-public information and this practice would violate security laws. Liability in these cases can extend to both the person to whom the insider disclosed inside information, and to you the insider, and would apply whether or not you derive any benefit from another's actions.

No Exception for Small Trades. This policy applies regardless of how small the trade is.

Other No Exception Conditions. It does not matter that you have decided to engage in a transaction before becoming aware of material non-public information or that the material non-public information did not affect your decision to engage in the transaction. It also does not matter that publicly disclosed

information about the Company might, aside from the material non-public information, provide a sufficient basis for engaging in the transaction

When Information is Public. It is also improper for you to enter a trade immediately after the Company has made a public announcement of material information, including earnings releases. For purposes of the SEC, you must wait until the beginning of the **second trading day**after material information has been released to the public (If, for example, the Company were to make an announcement after the close of the trading day on a Monday afternoon, you should not trade in the Company's securities until the beginning of the trading day on Wednesday). However, depending upon the form of the announcement and the nature of the information, it is possible that information may not be fully absorbed by the marketplace until later. Any questions as to whether information is non-public should be directed to the **COMPLIANCE OFFICER**. The term "trading day" means a day on which national stock exchanges are open for trading.

For the purpose of the FIEL, material inside information will be deemed to have been disclosed on the earlier of:

- twelve hours having lapsed since the information in question has been made known by the listed company in question to two different newspapers (not by any third party);
- the publication of the disclosure documents which have to be filed with the local finance bureau by a listed company, as prescribed by the FIEL, such as the annual report or extraordinary report;
- the publication of the information through TDnet, Timely Disclosure Network; or
- the registration document of the tender offer bid has been made public.

We impose certain "trading blackouts" to ensure that the Company's stockholders and the investing public will be afforded the time to receive the information and act upon it. These are discussed below under "Trading Blackouts."

Pre-Approval of Trades. To provide assistance in preventing inadvertent violations and avoiding even the appearance of an improper transaction (which could result, for example, if an employee engages in a trade while unaware of a pending major development), dated as all members of February 25, 2004, by the Board of Directors, officers and between the Parties, certain employees in a position to have access to material non-public information are subject to pre-approval by the provisions **COMPLIANCE OFFICER** of all transactions in Company stock (acquisitions, dispositions, transfers, etc.). Pre-approval provided by the **COMPLIANCE OFFICER** must be in writing and will be subject to a two week expiration, after which it must be renewed by the applicant in order to continue to be valid. See Exhibit B for a listing of those persons designated for this pre-approval requirement.

Pre-approval does not relieve anyone of their responsibility under government rules or under this Policy. You, whether subject to pre-approval or not, are responsible for adherence to this Policy, including, but not limited to: not trading on insider information; not trading during trading blackout periods; not trading for two days after earnings announcements; and not trading in securities on a short-term basis. Even if you are normally not subject to pre-approval are required to have pre-approval by the **COMPLIANCE OFFICER** for the sale of stock purchased in the open market that has been owned less than six months. (This rule

does not apply however to stock purchased upon the exercise of an employee stock option or an employee stock purchase plan.) If you are in doubt whether pre-approval is required,

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you should inquire with the **COMPLIANCE OFFICER**, or obtain pre-approval as a cautionary measure.

4. Director and Officer Filings.

The SEC requires of all Company Directors and Section 17.02 (Effects 16 officers of Termination) thereof. the Company (i.e. all persons listed on Exhibit C of this Policy) the initial reporting (on Form 3) and the reporting of subsequent changes (on Form 4) of ownership of the Company's stock, including the granting or exercising of stock options. (Form 4 must be filed before the end of the 2nd business day following a change of securities ownership.)

In addition to SEC reporting requirements, in the event of a sale transaction of the Company's stock by a director or executive officer, the Financial Services Agency ("**FSA**"), a Japan government organization which oversees securities and exchange in Japan, requires such individual to file a sales report ("**Sales Report by Officers or Principal Shareholders**") with the FSA by the fifteenth day of the immediately succeeding the month in which the sale took place. Such report must be submitted through the broker/dealer if the sale was affected through a broker/dealer, and by the individual if the sale was not affected through a broker/dealer; provided, however, that submission of the above report is not required in the following cases:

(a) in the case of sales of only fractional shares or odd lot shares;

(b) purchase of stock by a stockholding plan (limited to the case where the contribution amount at one time is less than 1 million yen);

(c) in the case where the purchase was made under an accumulative investment agreement through a securities company (limited to cases where the contribution amount at one time is less than 1 million yen);

(d) in the case where futures transactions of a group of different items of stock were conducted on a stock exchange;

(e) in the event that a stabilization transaction prescribed in Article 159, Paragraph 3 of the FIEL is conducted;

(f) in the case of a sale-and-repurchase of bonds (excluding stock options) with a predetermined repurchase price (limited to the case where the transaction is conducted only for the purpose of its own funding); or

(g) in the event that shares are newly acquired by the exercise of stock options, equity warrants, or stock purchase warrants which have already been obtained.

Trading Blackouts. From time to time, the Company may require that members of the Board of Directors, officers, selected employees and others suspend trading because of material events known to the Company and not yet disclosed to the public. In that event, these persons are advised not to engage in any transaction involving the purchase or sale of the Company's securities during that period and should not disclose to others the fact that they have been suspended from trading. The Parties hereby agree failure of the **COMPLIANCE OFFICER** to forthwith terminate designate a person as being subject to a specific blackout does not relieve that person of the Supply Compound Agreement obligation to suspend trading while aware of material non-public information.

In addition, the Company will also require the following mandatory trading blackouts:

- ***Quarterly Earnings Trading Blackouts*** – All members of the Board of Directors, officers, certain employees and other designated insiders (See Exhibit A) in a position to have

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access to material non-public information will be subject to a stock trading blackout period beginning the 15th day of the last month of a fiscal quarter until the beginning of the second trading day following the date earnings for Investigational Use that quarter are disclosed both in the U.S. and Japan (and for disclosure in Japan, in accordance with the section "When Information is Public").

- ***Trading After Earnings Announcements*** – If an earnings or earnings guidance announcement is made outside of KUR-1246, dated a regularly scheduled earnings trading blackout period, then all those listed in Exhibit A are restricted from engaging in trading transactions until the beginning of the second trading day following the date the announcement is made both in the U.S. and Japan (and for disclosure in Japan, in accordance with the section "When Information is Public").
- ***Special Blackout Periods*** – From time to time, the Company may also prohibit directors, officers, full- and part-time employees and agents (such as consultants and independent contractors) from engaging in transactions involving the Company's securities when, in the judgment of December 7, 2004, entered into the COMPLIANCE OFFICER, a trading blackout is warranted. The Company will generally impose special blackout periods when there are material developments known to the Company that have not yet been disclosed to the public. For example, the Company may impose a special blackout period in anticipation of announcing a significant transaction or business development. Special blackout periods may be declared for any reason.

Of course, no trading should be done at any time that a member of the Board of Directors, officer or employee is actually aware of a major undisclosed corporate development. There are no unconditional "safe harbors" for trades made at particular times, and you should exercise good judgment at all times. Even when a quarterly blackout period is not in effect, you may be prohibited from engaging in transactions involving the Company's securities because you possess material non-public information, are subject to a special blackout period or are otherwise restricted under this Policy.

5. Limited Exceptions

The following are certain limited exceptions to the restrictions imposed by and between the Parties Company under this Policy. Please be aware that even if a transaction is subject to an exception to this Policy, you will need to separately assess whether the transaction complies with applicable law. For example, even if a transaction is indicated as exempt from this Policy, you may need to comply with the "short-swing" trading restrictions under Section 16 of the Exchange Act, if applicable. You are responsible for complying with applicable law at all times.

A. Transactions Pursuant to a Trading Plan that Complies with SEC Rules

The SEC has enacted rules that provide an affirmative defense against alleged violations of U.S. federal insider trading laws for transactions pursuant to Section 9.01(a) of trading plans that meet certain requirements. In general, these rules, as set forth in Rule 10b5-1 under the License Agreement, and confirm that each Party shall have no outstanding obligation to the other Party thereunder. The Parties shall have no obligation to Exchange Act, provide for an affirmative defense if you enter into a commercial supply agreement between contract, provide instructions or adopt a written plan for trading securities when you are not aware of material non-public information. The contract, instructions or plan must (i) specify the Parties pursuant to Section 9.01(b) amount, price and date of the License Agreement.

(c) The Parties herby confirm that transaction, (ii) specify an objective method for determining the Agreement Concerning Performance of Study for Development Possibility (the "Study Performance Agreement"), dated as of October 13, 2011, entered into between the Parties shall terminate forthwith pursuant to Section 8.2(b) thereof, subject to the provisions of Section 8.3 thereof.

(d) Except as otherwise particularly set forth in this Agreement, any amount, price and all obligations date of the Parties under transaction and/or (iii) place any subsequent discretion for determining the License Agreement amount, price and date of the Study Performance Agreement shall lapse except for those accrued prior to and transaction in another person who is not, having been discharged at the time of the termination.

2. Return transaction, aware of US$1,250,000. material non-public information.

The Parties hereby acknowledge and confirm that MediciNova has already returned to Kissei, on October 26, 2021, the sum of US$1,250,000 that it received from Kissei Transactions made pursuant to

Sections 3.2(a) a written trading plan that (i) complies with the affirmative defense set forth in Rule 10b5-1, (ii) complies with the requirements set forth in Exhibit E hereto and 2.1(a) (iii) is approved by the **COMPLIANCE OFFICER**, are not subject to the restrictions in this Policy against

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trades made while aware of material non-public information or to the pre-clearance procedures or blackout periods established under this Policy. In approving a trading plan, the **COMPLIANCE OFFICER** may, in furtherance of the Study Performance Agreement objectives expressed in relation this Policy, impose criteria in addition to those set forth in Rule 10b5-1. You should therefore confer with the **COMPLIANCE OFFICER** prior to entering into any trading plan.

The SEC rules regarding trading plans are complex, and you must comply with them completely for your trading plan to be effective. The description provided above is only a summary, and the Company strongly advises that you consult with your personal legal advisor if you intend to adopt a trading plan. While trading plans are subject to the Phase 1 QTc Study Company's review and approval, you are ultimately responsible for compliance with Rule 10b5-1 and this Policy.

The **COMPLIANCE OFFICER** must keep a copy of each adopted trading plan. The Company may publicly disclose information regarding trading plans that you may enter (including but not limited to the information required by Regulation S-K Item 408), and you, or the Company on your behalf, will identify any Rule 10b5-1 transactions as such on Forms 4 and 5, if applicable.

B. Receipt and Vesting of Stock Options, Restricted Stock Units, Restricted Stock and Stock Appreciation Rights

The trading restrictions under this Policy do not apply to the grant or award of stock options, restricted stock units, restricted stock or stock appreciation rights issued or offered by the Company. The trading restrictions under this Policy also do not apply to the vesting, cancellation or forfeiture of stock options, restricted stock units, restricted stock or stock appreciation rights in accordance with applicable plans and agreements. The trading restrictions do apply, however, to any subsequent sales of any such securities or the common stock underlying such securities and any other market sale for the purpose of generating the cash needed to pay withholding taxes related to the settlement of restricted stock units or stock option exercises.

C. Cash or Cashless Net Exercise of Stock Options

The trading restrictions under this Policy do not apply to the exercise of stock options for cash under the Company's stock option plans. Likewise, the trading restrictions under this Policy do not apply to the exercise of stock options in a stock for stock exercise with the Company or an election to have the

Company withhold securities to cover tax obligations in connection with an option exercise. However, the trading restrictions under this Policy do apply to (i) the sale of any securities issued upon the exercise of a stock option, (ii) a cashless exercise of a stock option through a broker, because this involves selling a portion of the underlying shares to cover the costs of exercise, and (iii) any other market sale for the purpose of generating the cash needed to pay the exercise price of an option or to pay withholding taxes related to the settlement of restricted stock units or stock option exercises.

D. Stock Splits, Stock Dividends and Similar Transactions

The trading restrictions under this Policy do not apply to a change in the number of securities held as a result of a stock split or stock dividend applying equally to all securities of a class, or similar transactions.

E. Bona Fide Gifts and Inheritance

The trading restrictions under this Policy do not apply to bona fide gifts involving the Company's securities or transfers by will or the laws of descent and distribution. However, (i) if you have reason to believe that the recipient intends to sell the Company's securities while you are aware of material nonpublic information or, (ii) if (A) you are subject to the trading restrictions specified above under the

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heading "Trading Blackout Periods," and (B) you have reason to believe that the recipient intends to sell the Company securities during a blackout period, then the trading restrictions apply. In other words, you cannot use a gift to conduct a transaction that otherwise would be prohibited under this Policy.

In addition, the trading restrictions under this Policy apply to any gifted or inherited securities if the recipient, for example, an immediate family member, is subject to this Policy.

F. Change in Form of Ownership

Transactions that involve merely a change in the form in which you own securities are not subject to the trading restrictions under this Policy. For example, you may transfer shares to an inter vivos trust of which you are the sole beneficiary during your lifetime.

G. Other Exceptions

Any other exception from this Policy must be approved by the **COMPLIANCE OFFICER**, in consultation with the Board of Directors or an independent committee of the Board of Directors.

6. Additional Prohibited Transactions.

The Company believes it is improper and inappropriate for any Company personnel to engage in short-term or speculative transactions involving Company stock. We believe that this trading can reflect

badly on the Company and that Company personnel should not engage in any types of transactions that are a form of short-term "betting" for or against the Company. Accordingly, it is the Company's policy that you should not engage in any of the following activities with respect to securities of the Company:

- ***Trading in securities on a short-term basis*** — As a general rule, any Company stock purchased in the open market (i.e., not including stock purchased upon exercise of an employee stock option or an employee stock purchase plan) should be held for a minimum of six months and ideally longer. The top executives and members of the Board of Directors of the Company are already subject to the SEC's "short-swing" profit rule, which penalizes sales and purchases inside of any six-month period. If you wish to sell Company stock that was purchased in the open market and that has not been performed by MediciNova. owned less than six months, you must obtain prior written approval from the **COMPLIANCE OFFICER.**

- ***Purchases of Company stock on margin*** — This involves borrowing from a brokerage firm, bank or other entity in order to buy Company stock (other than in connection with a so-called "cashless" exercise of options under the Company's stock plans).
- ***Short sales of Company stock*** — This involves selling Company stock that you do not own in the expectation that the price of the stock will fall, or as part of an arbitrage transaction.
- ***Buying or selling puts or calls on Company stock*** — This includes options trading on any of the stock exchanges or futures exchanges.

7. Confidential Information and Communications with the Media.

Unauthorized disclosure of internal information relating to the Company (including information regarding new products, the Company's suppliers or customers) could cause competitive harm to the Company and in some cases could result in liability for the Company.

Unauthorized disclosure. You should not disclose internal information about the Company with anyone outside the Company, except as required in the performance of regular duties for the Company. In this regard, you are prohibited from posting internal information about the Company on the internet (bulletin board, blog chat room, etc.).

Communications with the media, securities analysts and investors. Communications on behalf of the Company with the media, securities analysts and investors must be made only by specifically designated representatives of the Company. Unless you have been expressly authorized to make such

communications, if you receive any inquiry relating to the Company from the media, a securities analyst or an investor, you should refer the inquiry to the **COMPLIANCE OFFICER**.

Safeguarding confidential information. Care must be taken to safeguard the confidentiality of internal information. For example, sensitive documents should not be left lying on desks, and visitors should not be left unattended in offices containing internal company documents.

Rumors. Rumors concerning the business and affairs of the Company may circulate from time to time. Our general policy is not to comment upon rumors. You should also refrain from commenting upon or responding to rumors and should refer any requests for comments or responses to the **COMPLIANCE OFFICER**.

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8. Company Assistance.

As previously stated, any person who has any questions about specific transactions may obtain additional guidance from the **COMPLIANCE OFFICER.**

Remember however that the ultimate responsibility for adhering to this Policy and avoiding improper transactions rests with you. In this regard, it is imperative that you use your best judgment.

9. Amendments.

The Company is committed to continuously reviewing and updating this Policy and any other Company policies and procedures. The Company therefore reserves the right to amend, alter or terminate this Policy at any time and for any reason, subject to applicable law. A current copy of the Company's policies regarding insider trading may be obtained by contacting the COMPLIANCE OFFICER.

10. Acknowledgements.

All employees and members of the Board of Directors will be required to acknowledge their understanding of, and an intent to comply with, this Statement of Company Policy by signing the attached acknowledgement. In addition, this Statement of Company Policy will be given to each person designated as an insider by the Company and the Company will request that the designated consultant, advisor or contractor to the Company acknowledge their understanding of, and an intent to comply with, this Statement of Company Policy by signing the attached acknowledgement.

MEDICINOVA, INC.
Statement of Company Policy

EXHIBIT A
List of Designated Insiders Subject to Blackout Periods, last updated

3. • Active Pharmaceutical Ingredient already Manufactured by Kissei. All full-time employees, part-time employees and interns of MediciNova, Inc. and its subsidiaries

(a) • MediciNova shall purchase from Kissei 7.15kg All members of the Active Pharmaceutical Ingredient (the "API") having already been manufactured by Kissei pursuant to Section 9.01(b) MediciNova's Board of the License Agreement for JPY16,000,000 per kilogram (JPY114,400,000 in the aggregate) within 60 days of the Effective Date. Directors

(b) • Kissei shall, as of the Effective Date, transfer and assign the Drug Master File (as referred to in Section 9.01(a) of the License Agreement) and any other associated information (collectively, the "DMF") in its possession as of the Effective Date, delivery of which shall be made within 60 days thereof at the expense of MediciNova, provided that the DMF shall be transferred and assigned only for the reasonable satisfaction of MediciNova for the general purpose of its pharmaceutical development practice. The transfer and assignment of the DMF shall become null and void retroactively if MediciNova provides Kissei with a written notice, within 7 days of its receipt of the delivery, that the DMF is not reasonably satisfactory to it for the said purpose. NOTWITHSTANDING ANYTHING TO THE CONTRARY CONTAINED IN THIS AGREEMENT, Signature Analytics, San Diego LLC

- Anderson Mori & Tomotsune
- Gunderson Dettmer Stough Villeneuve Franklin & Hachigian, LLP

MEDICINOVA, UNDERSTANDS AND ACKNOWLEDGES THAT ANY AND ALL OF THE API IS BEING PROVIDED "AS IS" AND THAT KISSEI IS NOT MAKING ANY REPRESENTATION OR WARRANTY, EXPRESSED OR IMPLIED, AS TO, INCLUDING

WITHOUT LIMITATION, THE QUALITY, COMPLETENESS OR FITNESS FOR A PARTICULAR PURPOSE.

IN WITNESS WHEREOF, the Parties, each by their duly authorized officers, have executed this Agreement as of the Effective Date. INC.

Kissei Pharmaceutical Co., Ltd. Statement of Company Policy

EXHIBIT B

List of All Designated Insiders Subject to Pre-Approval Procedures

- All full-time employees, part-time employees and interns of MediciNova, Inc. and its subsidiaries
- All members of MediciNova's Board of Directors

MEDICINOVA, INC.

Statement of Company Policy

EXHIBIT C

Individuals Subject to Section 16 Reporting and Liability Provisions

1.Directors

/s/ Mutsuo KanzawaName

By: Title(s)

By:

Yuichi Iwaki, M.D. Ph.D.	/s/ Yuichi Iwaki	Director, President and Chief Executive Officer
Carolyn Beaver		Director

Kazuko Matsuda	Director
Hideki Nagao	Director

Nicole Lemerond	Director
Mutsuo Kanzawa	Yuichi Iwaki
Chief Executive Officer	President and CEO

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Exhibit 21

Subsidiaries of the Registrant

2. Officers (including officers who are also directors)

	STATE	**JURISDICTION**
MEDICINOVA JAPAN INC. Name		JAPAN Title(s)
AVIGEN, INC	DE	US, DE CORPORATION
MEDICINOVA (EUROPE)LIMITED Yuichi Iwaki, M.D. Ph.D.		UK Director, President and Chief Executive Officer
MEDICINOVA EUROPE GmbH Jason Kruger		GERMANY Chief Financial Officer
Geoffrey O'Brien		Vice President
Kazuko Matsuda		Chief Medical Officer
David Crean		Chief Business Officer

MEDICINOVA, INC.

Statement of Company Policy EXHIBIT D

Material Facts Concerning Businesses of Listed Companies, Etc. per FIEL

1.Determined Facts

Listed Companies	Subsidiaries of Listed Companies
1. Issuance of shares (including preferred shares), equity warrants and stock options	
2. Reduction of capital	
3. Reduction of capital reserve or profit reserve	
4. Purchase of treasury stock	
5. Disposal of treasury stock	
6. Stock split	
7. Increase or decrease in dividends (including interim dividends)	
8. Exchange of stocks	1. Exchange of stocks
9. Transfer of stocks	2. Transfer of stocks
10. Merger	3. Merger
11. Corporate split	4. Corporate split
12. Transfer of the whole or any part of operations or business	5. Transfer of the whole or any part of operations or business
13. Dissolution (excluding dissolution by merger)	6. Dissolution (excluding dissolution by merger)
14. Corporatization of new products or new technologies	7. Corporatization of new products or new technologies

15. Formation or cancellation of a business alliance	8. Formation or cancellation of a business alliance
16. Assignment or acquisition of stocks or interests or operations which involves change in subsidiary	9. Assignment or acquisition of shares or interests which involves change in sub-subsidiary
17. Assignment or purchase of fixed assets	10. Assignment or acquisition of fixed assets

18. Suspension or abolition of the whole or any part of operations or business	11. Suspension or abolition of operation or business
19. Application for delisting of stocks from a stock exchange	
20. Application for cancellation of registration of stocks with the Japan Securities Dealers Association	
21. Petition for bankruptcy, institution of company rehabilitation procedures, or institution of company reorganization procedures	12. Petition for bankruptcy, institution of company rehabilitation procedures, or institution of company reorganization procedures
22. Launch of a new business (including corporatization of sales of new products or provision of new services)	13. Launch of a new business
23. Request for defensive purchase in order to counter takeover bids or any act similar thereto	
24. Offer pursuant to the provision of Article 74, Paragraph 5 of the Deposit Insurance Laws	14. Offer pursuant to the provision of Article 74, Paragraph 5 of the Deposit Insurance Laws

2.Occurred Facts

Listed Companies	Subsidiaries of Listed Companies

1. Damage caused by disasters or damage arising in the course of performance of business	1. Damage caused by disasters or damages arising in the course of performance of business
2. Change in principal shareholders	
3. Delisting of specified securities or options on specified securities, or any event of cancellation of registration	
4. Lawsuit concerning a claim regarding property rights or completion of such lawsuit	2. Lawsuit concerning a claim regarding property rights or completion of such lawsuit
5. Petition for provisional injunction or determination of such provisional injunction	3. Petition for provisional injunction or determination of such provisional injunction
6. Disposition by administrative agencies under laws and ordinances such as suspension of operation of business	4. Disposition by administrative agencies under laws and ordinances such as suspension of operation or business
7. Change in parent company	
8. Petition for bankruptcy by creditors or any party other than the relevant listed company	5. Petition for bankruptcy by creditors or any party other than the relevant subsidiary

9. Dishonor of drafts or checks or suspension of business by a clearing house	6. Dishonor of drafts or checks or suspension of business by a clearing house
10. Petition for bankruptcy of parent company	7. Petition for bankruptcy of sub-subsidiary
11. Potential for default due to occurrence of dishonor concerning debtors or principal debtors of guaranteed obligations	8. Potential for default due to occurrence of dishonor concerning debtors or principal debtors of guaranteed obligations
12. Suspension of transactions with major customers	9. Suspension of transactions with major customers
13. Discharge of debt or assumption or payment of a debt by a third party	10. Discharge of debt or assumption or payment of a debt by a third party
14. Discovery of resources	11. Discovery of resources

3. Matters Concerning Accounting

Listed Companies	Subsidiaries of Listed Companies
1. Turnover, ordinary profit or net profit	
2. Dividends or interim dividends	
3. Turnover, ordinary profit or net profit of corporate group	1. Turnover, ordinary profit or net profit * limited to the case where the subsidiary is a public company

* Occurrence of any difference from the latest estimate; if the estimate is not announced, occurrence of any difference from the historical data of the previous business year.

4. Comprehensive Provisions

Listed Companies	Subsidiaries of Listed Companies
Any material fact concerning the operation, business or assets of the company that affects the investment judgment of investors	Any material fact concerning the operation, business or assets of the company that affects the investment judgment of investors

5. Takeover bids or any act similar thereto (Article 167 of the F.I.E.L.)

MEDICINOVA, INC.

Statement of Company Policy EXHIBIT E

Requirements for Rule 10b5-1 Trading Plans

A Rule 10b5-1 “trading plan” involving purchases or sales of the Company’s securities must comply with the requirements of Rule 10b5-1 and must meet the following requirements:

1. The trading plan must be in writing and signed by the person adopting the trading plan.

2.The trading plan must be adopted at a time when:

- the person adopting the trading plan is not aware of any material non-public information ("**MNPI**"); and
- there is no quarterly, special or other trading blackout in effect with respect to the person adopting the trading plan.

3. The trading plan must be entered in good faith and not as part of a plan or scheme to evade the prohibitions of Rule 10b5-1 and the individual adopting the trading plan must act in good faith with respect to the plan through its duration.

4. In addition, directors and Section 16 officers of the Company (i.e., all persons listed on Exhibit C of this Policy) must represent in a trading plan at the time of its adoption (or modification) that (a) they are not aware of any MNPI about the Company or its securities, and (b) they are adopting (or modifying) the trading plan in good faith and not as part of a plan or scheme to evade the prohibitions of Rule 10b5-1.

5. The individual adopting the trading plan may not have entered into or altered a corresponding or hedging transaction or position with respect to the securities subject to the trading plan and must agree not to enter into any such transaction while the trading plan is in effect.

6.The first trade under the trading plan may not occur until:

- For directors and Section 16 officers of the Company (i.e., all persons listed on Exhibit C of this Policy), the later of (a) 90 calendar days after adoption of the trading plan or (b) two business days following the filing of the Form 10-Q or Form 10-K for the fiscal quarter in which the plan was adopted (but in any event, no more than 120 calendar days after the adoption of the trading plan).
- For all other persons, 30 calendar days after adoption of the trading plan.

7. The trading plan must have a minimum term of one year and a maximum term of two years (measured from the date the plan is effective).There is a limitation of one single-trade plan during any consecutive 12-month period.

8. The trading plan cannot overlap with another Rule 10b5-1 trading plan, unless one of the following exceptions applies:

- Eligible “sell-to-cover” transactions (i.e., authorizing the sale of securities as necessary to satisfy tax withholding obligations arising exclusively from the vesting of a compensatory award where the insider doesn’t otherwise exercise control over the timing of such sales) are not considered separate plans that count against this prohibition.

- A series of separate contracts with different broker-dealers that effectively function as a single trading plan are not considered overlapping plans.

- Trades under an existing trading plan can continue to run during the cooling-off period for a new trading plan if the following conditions are met: (i) trading under the new trading plan may not begin until after all trades under the existing trading plan are completed or expire without execution, and (ii) the applicable cooling off period under the new trading plan, running from the date of its adoption, has been met; *provided, however*, if the existing trading plan is terminated early (i.e., before its scheduled completion date), then the applicable cooling-off period for the new trading plan must run from the date of the termination of the existing trading plan.

9. Regarding material modifications (where such modifications change the amount, price or timing of the purchase or sale of securities pursuant to the plan, but does not include immaterial modifications):

- The trading plan may only be modified when the person modifying the trading plan is not aware of MNPI.

- The trading plan may only be modified when there is no quarterly, special or other blackout in effect with respect to the person modifying the plan.

- The first trade under the modified trading plan may only occur in accordance with the cooling off periods noted in item 6 above. The existing plan would remain in effect until the modified plan comes into effect.

- The modified trading plan must have a minimum duration of one year and a maximum term of two years (measured from the date the plan is effective).

10. A person may only modify a trading plan once in a one-year period.

11. If the person that adopted the trading plan terminates the plan prior to its stated duration, he or

she may not trade in the Company's securities until the cooling off periods noted in item 6 above have been met.

12. The Company must be promptly notified of any modification or termination of the trading plan, including any suspension of trading under the plan.

13. If the trading plan grants discretion to a stockbroker or other person with respect to the execution of trades under the plan:

- trades made under the trading plan must be executed by someone other than the stockbroker or other person that executes trades in other securities for the person adopting the trading plan;

- the person adopting the trading plan may not confer with the person administering the trading plan regarding the Company or its securities; and
- the person administering the trading plan must provide prompt notice to the Company of the execution of a transaction pursuant to the plan.

14. All transactions under the trading plan must be in accordance with applicable law.

15. The trading plan (including any modified trading plan) must meet such other requirements as the **COMPLIANCE OFFICER** may determine.

16. The **COMPLIANCE OFFICER** must approve and keep a copy of each adopted trading plan.

MEDICINOVA, INC.

4275 Executive Square, Suite 650 La Jolla, CA 92037

Re: Certification of the MediciNova, Inc. Statement of Company Policy on Securities Trades by Company Personnel and Confidential Information

Dear Employee, Board Member, Consultant, Advisor or Contractor to the Company:

Enclosed is a copy of the MediciNova, Inc. Statement of Company Policy covering securities trades by company personnel and designated insiders and safeguarding confidential information. As you will see from the Statement of Company Policy, the consequences of an insider trading violation can be severe to both the individual involved and the Company.

Please take a few minutes now to read the enclosed Statement of Company Policy and then sign and return the attached copy of this letter.

Sincerely,

Yuichi Iwaki

President & Chief Executive Officer

ACKNOWLEDGMENT

The undersigned hereby acknowledges that he/she has read and understands, and agrees to comply with, the Statement of Company Policy covering securities trades by Company personnel and designated insiders and safeguarding confidential information, a copy of which was distributed with this letter.

Dated:

Signature:

Print name:

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

MediciNova, Inc.
La Jolla, California

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 S-3 (No. 333-267094, 333-252592 and 333-233201) 333-214830) and Form S-8 (No. 333-264938, 333-232239, 333-219491, 333-190490, 333-

151808, 333-141694 and 333-122665) of MediciNova, Inc. of our report dated February 16, 2023 February 15, 2024, relating to the consolidated financial statements, which appears in this Form 10-K.

/s/ BDO USA, LLP P.C.

San Diego, California
February 16, 2023 15, 2024

Exhibit 31.1

CERTIFICATION OF THE PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Yuichi Iwaki, certify that:

1. I have reviewed this Annual Report on Form 10-K for the fiscal year ended December 31, 2022 December 31, 2023 of MediciNova, Inc.;

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

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

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

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated

subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

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

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

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

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

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

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

/s/ Yuichi Iwaki

Yuichi Iwaki, M.D., Ph.D.

President and Chief Executive Officer

(Principal executive officer)

Date: February 16, 2023 February 15, 2024

Exhibit 31.2

CERTIFICATION OF THE PRINCIPAL FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Jason Kruger, certify that:

1. I have reviewed this Annual Report on Form 10-K for the fiscal year ended December 31, 2022 December 31, 2023 of MediciNova, Inc.;

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

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

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

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

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

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

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

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

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

financial information; and

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

/s/ Jason Kruger

Jason Kruger

Chief Financial Officer

(Principal financial officer)

Date: February 16, 2023 February 15, 2024

Exhibit 32.1

CERTIFICATION OF THE PRINCIPAL EXECUTIVE OFFICER
Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
(Subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code)

In connection with the Annual Report on Form 10-K of MediciNova, Inc. (the "Company") for the period ended December 31, 2022 December 31, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Yuichi Iwaki, M.D., Ph.D., as President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

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

Date: February 16, 2023 February 15, 2024

/s/ Yuichi Iwaki

Yuichi Iwaki, M.D., Ph.D.

President and Chief Executive Officer

(Principal executive officer)

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. § 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing. A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

Exhibit 32.2

CERTIFICATION OF THE PRINCIPAL FINANCIAL OFFICER
Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
(Subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code)

In connection with the Annual Report on Form 10-K of MediciNova, Inc. (the "Company") for the period ended December 31, 2022 December 31, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"),

I, Jason Kruger, as Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

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

Date: February 16, 2023 February 15, 2024

/s/ Jason Kruger

Jason Kruger

Chief Financial Officer

(Principal financial officer)

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. § 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing. A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

Exhibit 97.1

MEDICINOVA, INC. POLICY FOR THE

RECOVERY OF ERRONEOUSLY AWARDED COMPENSATION

1. **Purpose**. The purpose of this Policy is to describe the circumstances in which Executive Officers will be required to repay or return Erroneously Awarded Compensation to members of the Company Group. This Policy is designed to comply with, and shall be interpreted to be consistent with, Section 10D of the Securities Exchange Act of 1934, as amended, Rule 10D-1 promulgated thereunder and the Listing Standards. Each Executive Officer shall be required to sign and return to the Company the Acknowledgment Form attached hereto as Exhibit A pursuant to which such Executive Officer will agree to be bound by the terms of and comply with this Policy.

2. **Administration**. This Policy shall be administered by the Committee. The Committee is authorized to interpret and construe this Policy and to make all determinations, and take all actions, necessary, appropriate or advisable for the administration of this Policy. Any determinations and interpretations made by the Committee shall be final and binding on all affected individuals, and need not be uniform with respect to each individual covered by the Policy.

3. **Definitions**. As used in this Policy, the following capitalized terms shall have the meanings set forth below.

(a) "***Accounting Restatement***" shall mean an accounting restatement of the Company's financial statements due to the Company's material noncompliance with any financial reporting requirement under U.S. securities laws, including any required accounting restatement (i) that corrects an error in previously issued financial statements that is material to the

previously issued financial statements (a “Big R” restatement), or (ii) that corrects an error that is not material to previously issued financial statements, but would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period (a “little r” restatement). An Accounting Restatement does not include situations in which financial statement changes did not result from material noncompliance with financial reporting requirements, such as, but not limited to, retrospective: (i) application of a change in accounting principles; (ii) revision to reportable segment information due to a change in the structure of the Company’s internal organization; (iii) reclassification due to a discontinued operation; (iv) application of a change in reporting entity, such as from a reorganization of entities under common control; (v) adjustment to provisional amounts in connection with a prior business combination; and (vi) revision for stock splits, reverse stock splits, stock dividends or other changes in capital structure.

(b) “***Board***” shall mean the Board of Directors of the Company.

(c) “***Clawback Eligible Incentive Compensation***” shall mean, in connection with an Accounting Restatement and with respect to each individual who served as an Executive Officer at any time during the applicable performance period for any Incentive-Based Compensation (whether or not such Executive Officer is serving at the time the Erroneously Awarded Compensation is required to be repaid to the Company Group), all Incentive-Based Compensation Received by such Executive Officer (i) on or after the effective date of the Listing Standards (even if such Incentive-Based Compensation was approved, awarded, granted or paid prior to the effective date of the Listing Standards), (ii) after beginning service as an Executive Officer, (iii) while the Company has a class of securities listed on a national securities exchange or a national securities association, and (iv) during the applicable Clawback Period.

(d) “***Clawback Period***” shall mean, with respect to any Accounting Restatement, the three completed fiscal years of the Company immediately preceding the Restatement Date and any transition period (that results from a change in the Company’s fiscal year) of less than nine months within or immediately following those three completed fiscal years.

(e) “***Committee***” shall mean the Compensation Committee of the Board.

(f) “***Company***” shall mean MediciNova, Inc., a Delaware corporation.

(g) “***Company Group***” shall mean the Company, together with each of its direct and indirect subsidiaries.

(h) “***Effective Date***” shall mean the effective date of this Policy, which date is December 1, 2023.

(i) "***Erroneously Awarded Compensation***" shall mean, with respect to each Executive Officer in connection with an Accounting Restatement, the amount of Clawback Eligible Incentive Compensation that exceeds the amount of Incentive-Based Compensation that otherwise would have been Received had it been determined based on the restated amounts as reflected in the Accounting Restatement, computed without regard to any taxes paid. For Incentive-Based Compensation based on (or derived from) stock price or total shareholder return, where the amount of Erroneously Awarded Compensation is not subject to mathematical recalculation directly from the information in the applicable Accounting Restatement, the amount shall be determined by the Committee based on a reasonable estimate of the effect of the Accounting Restatement on the stock price or total shareholder return upon which the Incentive-Based Compensation was Received (in which case, the Company shall maintain documentation of such determination of that reasonable estimate and provide such documentation to Nasdaq).

(j) "***Executive Officer***" shall mean each individual who is or was designated as an "officer" of the Company in accordance with 17 C.F.R. 240.16a-1(f). Identification of an executive officer for purposes of this Policy would include, at a minimum, executive officers identified pursuant to 17 C.F.R. 229.401(b). As of the Effective Date (and subject to later amendments to the above-referenced rules), Executive Officer covers the Company's president, principal financial officer, principal accounting officer (or if there is no such accounting officer, the controller), any vice-president of the Company in charge of a principal business unit, division or function (such as sales, administration or finance), any other officer who performs a significant policy-making function, or any other person (including any executive officer of the Company's affiliates including a parent or subsidiary of the Company) who performs similar policy-making functions for the Company.

(k) "***Financial Reporting Measures***" shall mean measures that are determined and presented in accordance with the accounting principles used in preparing the Company's financial statements (including "non-GAAP financial measures," such as those appearing in earnings releases), and any measures that are derived wholly or in part from such measures. For the avoidance of doubt, a Financial Reporting Measure need not be presented within the Company's financial statements or included in a filing with the SEC. Stock price and total shareholder return shall for purposes of this Policy also be considered Financial Reporting Measures.

(l) "***Incentive-Based Compensation***" shall mean any compensation that is granted, earned or vested based wholly or in part upon the attainment of a Financial Reporting Measure. For the sake of clarity, examples of compensation that is not Incentive-Based Compensation include, but are not limited to: (i) base salaries; (ii) discretionary cash bonuses; (iii) awards (either of cash or equity) that are based solely upon subjective, strategic or operational metrics or measures; and (iv) equity awards that vest solely upon continued service or the passage of time.

(m) "***Listing Standards***" shall mean Nasdaq Listing Rule 5608.

(n) "***Nasdaq***" shall mean The Nasdaq Stock Market.

(o) "***Policy***" shall mean this Policy for the Recovery of Erroneously Awarded Compensation, as the same may be amended, restated, supplemented or otherwise modified from time to time.

(p) "***Received***" shall, with respect to any Incentive-Based Compensation, mean actual or deemed receipt, and Incentive-Based Compensation shall be deemed received in the Company's fiscal period during which the Financial Reporting Measure specified in the Incentive-Based Compensation award is attained, even if grant or payment of the Incentive-Based Compensation occurs after the end of that period.

(q) "***Restatement Date***" shall mean the earlier to occur of (i) the date the Board, a committee of the Board or the officers of the Company authorized to take such action if Board action is not required, concludes, or reasonably should have concluded, that the Company is required to prepare an Accounting Restatement, or (ii) the date a court, regulator or other legally authorized body directs the Company to prepare an Accounting Restatement, in each case regardless of if or when the restated financial statements are filed.

(r) "***SEC***" shall mean the U.S. Securities and Exchange Commission.

4. **Required Recovery of Erroneously Awarded Compensation**.

(a) In the event the Company is required to prepare an Accounting Restatement, the Committee shall determine the amount of any Erroneously Awarded Compensation for each Executive Officer in connection with such Accounting Restatement, shall thereafter provide each Executive Officer with a written notice containing the amount of Erroneously Awarded Compensation and a demand for repayment or return, as applicable, and shall take all other actions necessary and appropriate to recover such Erroneously Awarded Compensation from the applicable Executive Officers reasonably promptly.

(b) The Committee shall determine, in its sole discretion, the timing and method for recovering Erroneously Awarded Compensation reasonably promptly based on all applicable facts and circumstances and taking into account the time value of money and the cost to shareholders of delaying recovery. Such methods may include, without limitation, (i) seeking reimbursement of all or part of any cash or equity-based award, (ii) cancelling prior cash or equity-based awards, whether vested or unvested or paid or unpaid, (iii) cancelling or offsetting against any planned future cash or equity-based awards, (iv) forfeiture of deferred compensation, subject to compliance with Section 409A of the Internal Revenue Code and the regulations promulgated thereunder, and (v) any other method authorized by applicable law or contract. Subject to compliance with any applicable law, the Committee may effect recovery under this Policy (i) from any amount otherwise payable to the Executive Officer, including

amounts payable to such individual under any otherwise applicable Company plan or program, including base salary, bonuses or commissions, and compensation previously deferred by the Executive Officer, and (ii) from any amount of compensation approved, awarded, granted, payable or paid to the Executive Officer prior to, on or after the effective date of the Listing Standards. For the avoidance of doubt, except as set forth in Section 4(d) below, in no event may the Company Group accept an amount that is less than the amount of Erroneously Awarded Compensation in satisfaction of an Executive Officer's obligations hereunder.

(c) To the extent that an Executive Officer fails to repay all Erroneously Awarded Compensation to the Company Group when due, the Company shall, or shall cause one or more other members of the Company Group to, take all actions reasonable and appropriate to recover such Erroneously Awarded Compensation from the applicable Executive Officer. The applicable Executive Officer shall be required to reimburse the Company Group for any and all expenses reasonably incurred (including legal fees) by the Company Group in recovering such Erroneously Awarded Compensation in accordance with the immediately preceding sentence.

(d) Notwithstanding anything herein to the contrary, the Company shall not be required to recover Erroneously Awarded Compensation from any Executive Officer if the following conditions are met and the Committee determines that recovery would be impracticable:

(i) The direct expenses paid to a third party to assist in enforcing the Policy against an Executive Officer would exceed the amount to be recovered, after the Company has made a reasonable attempt to recover the applicable Erroneously Awarded Compensation, documented such attempt(s) and provided such documentation to Nasdaq;

(ii) Recovery would violate home country law of the Company where that law was adopted prior to November 28, 2022, after the Company has obtained an opinion of home country counsel, acceptable to Nasdaq, that recovery would result in such a violation and a copy of the opinion is provided to Nasdaq; or

(iii) Recovery would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of the Company Group, to fail to meet the requirements of 26 U.S.C. 401(a)(13) or 26 U.S.C. 411(a) and regulations thereunder.

5. **Reporting and Disclosure**. The Company shall file all disclosures with respect to this Policy in accordance with the requirements of the federal securities laws, including the disclosure required by the applicable SEC filings. The Company shall also file a copy of this Policy and any amendments thereto as an exhibit to its annual report on Form 10-K.

6. **No Indemnification of Executive Officers**. Notwithstanding the terms of any indemnification or insurance policy or any contractual arrangement with any Executive Officer that may be interpreted to the contrary, no member of the

Company Group shall be permitted to indemnify any Executive Officer against, or pay or reimburse the premiums for an insurance policy to cover, (i) the loss of any Erroneously Awarded Compensation that is repaid, returned or recovered pursuant to the terms of this Policy, or (ii) any claims relating to the Company Group's enforcement of its rights under this Policy. Further, no member of the Company Group shall enter into any agreement that exempts any Incentive-Based Compensation from the application of this Policy or that waives the Company Group's right to recovery of any Erroneously Awarded Compensation, and this Policy shall supersede any such agreement (whether entered into before, on or after the Effective Date).

7. **Committee Indemnification**. Any members of the Committee, and any other members of the Board who assist in the administration of this Policy, shall not be personally liable for any action, determination or interpretation made with respect to this Policy and shall be fully indemnified by the Company to the fullest extent under applicable law and Company policy with respect to any such action, determination or interpretation. The foregoing sentence shall not limit any other rights to indemnification of the members of the Board under applicable law or Company policy.

8. **Effective Date**. This Policy shall be effective as of the Effective Date.

9. **Amendment**; **Termination**. The Committee may amend, modify, supplement, rescind or replace all or any portion of this Policy at any time and from time to time in its discretion and shall amend this Policy as it deems necessary, including as and when it determines that it is legally required by any federal securities laws, SEC rule or the rules of any national securities exchange or national securities association on which the Company's securities are listed. The Committee may terminate this Policy at any time. Notwithstanding anything in this Section 9 to the contrary, no amendment or termination of this Policy shall be effective if such amendment or termination would (after taking into account any actions taken by the Company contemporaneously with such amendment or termination) cause the Company to violate any federal securities laws, SEC rule or the rules of any national securities exchange or national securities association on which the Company's securities are listed.

10. **Other Recoupment Rights; Company Claims**.

(a) The Committee intends that this Policy will be applied to the fullest extent of the law and with respect to all Incentive-Based Compensation granted to an Executive Officer, whether pursuant to a pre-existing contract or arrangement, or one that is entered into after the Effective Date. Any right of recoupment under this Policy is in addition to, and not in lieu of, any other remedies or rights of recoupment that may be available to the Company Group under applicable law, regulation or rule or pursuant to the terms of any similar policy in any

employment agreement, equity award agreement or similar agreement and any other legal remedies available to the Company Group.

(b) Nothing contained in this Policy, and no recoupment or recovery as contemplated by this Policy, shall limit any claims, damages or other legal remedies the Company or any of its affiliates may have against an Executive Officer arising out of or resulting from any actions or omissions by the Executive Officer.

11. **Successors**. This Policy shall be binding and enforceable against all Executive Officers and their beneficiaries, heirs, executors, administrators or other legal representatives.

* * *

Exhibit A

MEDICINOVA, INC. POLICY FOR THE

RECOVERY OF ERRONEOUSLY AWARDED COMPENSATION

ACKNOWLEDGMENT FORM

By signing below, the undersigned acknowledges and confirms that the undersigned has received and reviewed a copy of the MediciNova, Inc. Policy for the Recovery of Erroneously Awarded Compensation (as may be amended, restated, supplemented or otherwise modified from time to time, the "***Policy***"). Capitalized terms used but not otherwise defined in this Acknowledgment Form (this "***Acknowledgment Form***") shall have the meanings ascribed to such terms in the Policy.

By signing this Acknowledgment Form, the undersigned acknowledges and agrees that the undersigned is and will continue to be subject to the Policy and that the Policy will apply both during and after the undersigned's employment with the Company Group. Further, by signing below, the undersigned agrees to abide by the terms of the Policy, including, without limitation, by promptly returning any Erroneously Awarded Compensation (as defined in the Policy) to the Company Group to the extent required by, and in a manner permitted by, the Policy. In the event of any inconsistency between the Policy and the terms of any employment agreement to which the

undersigned is a party, or the terms of any compensation plan, program or agreement under which any compensation has been granted, awarded, earned or paid, the terms of the Policy shall govern.

_____ Signature

Print Name

Title

Date

DISCLAIMER

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