UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2023

☐ **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:

Common Stock, $0.001 par value	**MNOV**	**The Nasdaq Stock Market LLC**
(Title of each class)	(Trading symbol(s))	(Name of each exchange on which registered)

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 the definitions of "accelerated filer", "large 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 is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of November 7, 2023, the registrant had 49,046,246 shares of Common Stock ($0.001 par value) outstanding.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This quarterly report on Form 10-Q, in particular "Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations," and the information incorporated by reference herein contains “forward-looking statements”. 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. Considering 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 Food and Drug Administration or foreign regulatory approval for our product candidates in a timely manner;
- Unsuccessful clinical trials stemming from clinical trial designs, failure to enroll a sufficient number of patients, undesirable side effects and other safety concerns;
- Inability to demonstrate sufficient efficacy of product candidates;
- Reliance on the success of our MN-166 (ibudilast) and MN-001 (tipelukast) product candidates;
- Delays in commencement or completion of clinical trials or suspension or termination of clinical trials;
- Loss of our licensed rights to develop and commercialize a product candidate as a result of the termination of the underlying licensing agreement;
- Competitors may develop products rendering our product candidates obsolete and noncompetitive;
- The widespread outbreak of an illness or any other communicable disease, such as COVID-19, which would lead 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 party reimbursement;
- Disputes or other developments concerning our intellectual property rights;
- Actual and anticipated fluctuations in our quarterly or annual operating results;
- Price and volume fluctuations in the overall stock markets;
- 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.

MEDICINOVA, INC.

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PART I. FINANCIAL INFORMATION

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS.

MEDICINOVA, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)

	September 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 51,507,361	$ 18,505,493
Accounts receivable	1,000,000	—
Prepaid expenses and other current assets	488,786	499,403
Investments	—	39,982,213
Total current assets	52,996,147	58,987,109
Goodwill	9,600,240	9,600,240
In-process research and development	4,800,000	4,800,000
Property and equipment, net	51,241	45,269
Right-of-use asset	617,866	629,495
Other non-current assets	71,067	92,792
Total assets	$ 68,136,561	$ 74,154,905
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 736,896	$ 424,646
Accrued liabilities and other current liabilities	1,859,389	2,605,308
Operating lease liability	205,394	157,505
Total current liabilities	2,801,679	3,187,459
Deferred tax liability	201,792	201,792
Other non-current liabilities	463,838	523,619
Total liabilities	3,467,309	3,912,870
Commitments and contingencies (Note 4)		
Stockholders' equity:		
Common stock, $0.001 par value; 100,000,000 shares authorized at September 30, 2023 and December 31, 2022; 49,046,246 and 49,046,246 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	49,046	49,046
Additional paid-in capital	478,386,566	477,438,451
Accumulated other comprehensive loss	(123,752)	(115,285)
Accumulated deficit	(413,642,608)	(407,130,177)
Total stockholders' equity	64,669,252	70,242,035
Total liabilities and stockholders' equity	$ 68,136,561	$ 74,154,905

See accompanying notes.

MEDICINOVA, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(Unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2023	2022	2023	2022
Revenues	$ 1,000,000	$ —	$ 1,000,000	$ —
Operating expenses:				
Research, development and patents	794,706	2,454,203	4,007,117	7,131,168
General and administrative	1,352,182	1,443,264	4,403,044	4,266,246
Total operating expenses	2,146,888	3,897,467	8,410,161	11,397,414
Operating loss	(1,146,888)	(3,897,467)	(7,410,161)	(11,397,414)
Interest income	437,934	253,755	1,398,400	382,369
Other expense	(14,153)	(8,472)	(500,670)	(52,554)
Net loss applicable to common stockholders	$ (723,107)	$ (3,652,184)	$ (6,512,431)	$ (11,067,599)
Basic and diluted net loss per common share	$ (0.01)	$ (0.07)	$ (0.13)	$ (0.23)
Shares used to compute basic and diluted net loss per common share	49,046,246	49,046,246	49,046,246	49,045,037
Net loss applicable to common stockholders	$ (723,107)	$ (3,652,184)	$ (6,512,431)	$ (11,067,599)
Other comprehensive loss, net of tax:				
Foreign currency translation adjustments	(2,712)	(5,972)	(8,467)	(25,387)
Comprehensive loss	$ (725,819)	$ (3,658,156)	$ (6,520,898)	$ (11,092,986)

See accompanying notes.

MEDICINOVA, INC.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(Unaudited)

	Nine Months Ended September 30, 2023					
	Common stock		Additional paid-in capital	Accumulated other comprehensive loss	Accumulated deficit	Total stockholders' equity
	Shares	Amount				
Balance at December 31, 2022	49,046,246	$ 49,046	$ 477,438,451	$ (115,285)	$ (407,130,177)	$ 70,242,035
Share-based compensation	—	—	403,263	—	—	403,263
Net loss	—	—	—	—	(2,917,504)	(2,917,504)
Foreign currency translation adjustments	—	—	—	(1,542)	—	(1,542)
Balance at March 31, 2023	49,046,246	49,046	477,841,714	(116,827)	(410,047,681)	67,726,252
Share-based compensation	—	—	325,710	—	—	325,710
Net loss	—	—	—	—	(2,871,820)	(2,871,820)
Foreign currency translation adjustments	—	—	—	(4,213)	—	(4,213)
Balance at June 30, 2023	49,046,246	49,046	478,167,424	(121,040)	(412,919,501)	65,175,929
Share-based compensation			219,142			219,142
Net loss					(723,107)	(723,107)
Foreign currency translation adjustments				(2,712)		(2,712)
Balance at September 30, 2023	49,046,246	$ 49,046	$ 478,386,566	$ (123,752)	$ (413,642,608)	$ 64,669,252

	Nine Months Ended September 30, 2022					
	Common stock		Additional paid-in capital	Accumulated other comprehensive loss	Accumulated deficit	Total stockholders' equity
	Shares	Amount				
Balance at December 31, 2021	49,043,246	$ 49,043	$ 476,788,012	$ (98,877)	$ (393,061,094)	$ 83,677,084
Share-based compensation	—	—	81,053	—	—	81,053
Net loss	—	—	—	—	(3,386,417)	(3,386,417)
Foreign currency translation adjustments	—	—	—	(7,435)	—	(7,435)
Balance at March 31, 2022	49,043,246	49,043	476,869,065	(106,312)	(396,447,511)	80,364,285
Share-based compensation	—	—	274,502	—	—	274,502
Issuance of common stock for option exercises	3,000	3	7,917	—	—	7,920
Net loss	—	—	—	—	(4,028,998)	(4,028,998)
Foreign currency translation adjustments	—	—	—	(11,980)	—	(11,980)
Balance at June 30, 2022	49,046,246	49,046	477,151,484	(118,292)	(400,476,509)	76,605,729
Share-based compensation	—	—	158,298	—	—	158,298
Net loss	—	—	—	—	(3,652,184)	(3,652,184)
Foreign currency translation adjustments	—	—	—	(5,972)	—	(5,972)
Balance at September 30, 2022	49,046,246	$ 49,046	$ 477,309,782	$ (124,264)	$ (404,128,693)	$ 73,105,871

See accompanying notes.

MEDICINOVA, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)

	Nine months ended September 30,	
	2023	**2022**
Operating activities:		
Net loss	$ (6,512,431)	$ (11,067,599)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash stock-based compensation	948,115	513,853
Depreciation and amortization	14,803	13,376
Loss on disposal of investments	102,513	—
Non-cash interest on investments	—	(21,849)
Loss on disposal of property and equipment	371	—
Change in carrying amount of right-of-use asset	146,205	151,123
Changes in assets and liabilities:		
Accounts receivable	(1,000,000)	—
Prepaid expenses and other assets	(27,478)	(49,947)
Accounts payable, accrued liabilities and other liabilities	(457,675)	1,660,250
Operating lease liabilities	(146,401)	(103,726)
Net cash used in operating activities	(6,931,978)	(8,904,519)
Investing activities:		
Proceeds from disposal of investments	39,929,015	—
Purchases of investments	—	(10,000,000)
Acquisitions of property and equipment	(21,321)	—
Net cash provided by (used in) investing activities	39,907,694	(10,000,000)
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	26,152	(27,092)
Net change in cash and cash equivalents	33,001,868	(18,923,691)
Cash and cash equivalents, beginning of period	18,505,493	71,430,954
Cash and cash equivalents, end of period	$ 51,507,361	$ 52,507,263
Supplemental disclosure of non-cash investing activities:		
Right-of-use asset obtained in exchange for operating lease liability	$ 139,001	$ —

See accompanying notes.

1. Interim Financial Information

Organization and Business

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

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States (GAAP) for interim financial information and with the instructions of the Securities and Exchange Commission (SEC) on Form 10-Q and Rule 8-03 of Regulation S-X. Accordingly, they do not include all the information and disclosures required by GAAP for complete financial statements. In the opinion of management, the condensed consolidated financial statements include all adjustments necessary, which are of a normal and recurring nature, for the fair presentation of the Company's financial position and of the results of operations and cash flows for the periods presented. The accompanying unaudited condensed consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries.

These financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto for the year ended December 31, 2022 included in the Company's Amendment No. 1 to Annual Report on Form 10-K filed with the SEC. The results of operations for the interim period shown in this report are not necessarily indicative of the results that may be expected for any other interim period or for the full year. The balance sheet at December 31, 2022 has been derived from the audited financial statements at that date but does not include all the information and footnotes required by GAAP for complete financial statements.

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.

Cash and Cash Equivalents

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

Accounts Receivable

Accounts receivable is recorded net of allowance for credit losses. There was no allowance for credit losses required as of September 30, 2023 (see Note 2). Accounts receivable balance as of January 1, 2022 was $0.

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.

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 $0.7 million and $2.4 million for the three months ended September 30, 2023 and 2022, respectively, and $3.7 million and $6.8 million for the nine months ended September 30, 2023 and 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 $0.1 million for the three months ended September 30, 2023 and 2022, respectively, and $0.3 million for the nine months ended September 30, 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, the Company entered into an agreement with the Biomedical Advanced Research and Development Authority (BARDA), part of the Office of the Assistant Secretary for Preparedness and Response 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 acute respiratory distress syndrome (ARDS) and acute lung injury (ALI). Under the agreement, BARDA agreed to provide federal funding for specified pre-clinical 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 funding of $0.7 million as an offset to research and development costs for the three and nine months ended September 30, 2023.

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.

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 components. 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 expenses. As most of 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.

Use of Estimates

The preparation of the consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the condensed consolidated financial statements and the accompanying notes. Actual results could differ from those estimates.

Recently Issued Accounting Pronouncements

In June 2016, the 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.

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 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.

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 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 products and there is no further substantive service effort required by the Company. In 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 one clinical development milestone, triggering a milestone payment of $1.0 million. Accordingly, the Company recognized revenue and accounts receivable of $1.0 million as of and for the three and nine months ended September 30, 2023. The Company subsequently received payment of the $1.0 million in October 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 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 September 30, 2023 and December 31, 2022, were as follows:

	September 30, 2023		December 31, 2022		
	Carrying Amount	Fair Value	Carrying Amount	Fair Value	Valuation Inputs
Cash and cash equivalents:					
Money market funds	$ 772,195	$ 772,195	$ 704,882	$ 704,882	Level 1
Investments					
Bank certificates of deposit	—	—	$ 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. 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 2025 with an auto-renewal, two-year extension. 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 balance sheet.

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

	Three months ended September 30,		Nine months ended September 30,	
	2023	2022	2023	2022
Cash paid for operating lease liabilities	$ 64,024	$ 62,045	$ 189,622	$ 128,280
Operating lease costs	64,011	64,004	190,240	176,896

	September 30, 2023	December 31, 2022
Current operating lease liabilities	$ 205,394	$ 157,505
Non-current operating lease liabilities	463,838	523,619
Total operating lease liabilities	$ 669,232	$ 681,124
Weighted-average remaining lease term (in years)	3.06	3.90
Weighted-average discount rate	9.1%	9.8%

Maturities of operating lease liabilities as of September 30, 2023 were as follows:	
2023 (remaining three months)	$ 63,599
2024	261,420
2025	227,690
2026	206,483
2027	17,269
Thereafter	—
Total minimum payments	776,461
Less imputed interest	(107,229)
Total lease liabilities	$ 669,232

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 specified 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 three and nine months ended September 30, 2023 and 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 September 30, 2023. For all other products, future potential milestone payments related to development milestones and commercialization milestones totaled $16.5 million as of September 30, 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.

5. Stock-based Compensation

Stock Incentive Plans

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

In June 2023, the Company adopted the 2023 Equity Incentive Plan, or 2023 Plan, under which the Company may grant stock options, stock appreciation rights, restricted stock, restricted stock units and other awards to individuals who are then employees, officers, non-employee directors or consultants of the Company or its subsidiaries. The 2023 Plan is the successor to the 2013 Plan. A total of 8,700,000 shares of common stock are reserved for issuance under the 2023 Plan. The number of shares of common stock that may be issued under the 2023 Plan is equal to the sum of (a) shares subject to awards granted under the 2013 Plan that were outstanding upon expiration of the 2013 Plan and are subsequently forfeited, expire or lapse unexercised or unsettled and shares issued pursuant to awards granted under the 2013 Plan that were outstanding upon expiration of the 2013 Plan and are subsequently forfeited to or reacquired by the Company and (b) shares reserved under the 2013 Plan that were not issued or subject to outstanding awards under the 2013 Plan upon expiration of the 2013 Plan. While a maximum of 9,934,567 shares may become available for issuance under the 2023 Plan from the 2013 Plan, since this figure assumes that all awards outstanding under the 2013 Plan upon expiration of the 2013 Plan will be forfeited, the Company expects the actual number of shares added to the 2023 Plan to be less. In general, to the extent that awards under the 2023 Plan are forfeited, cancelled or expire for any reason before being exercised or settled in full, the shares subject to such awards will again become available for issuance under the 2023 Plan. If stock appreciation rights are exercised or restricted stock units are settled, then only the number of shares (if any) actually issued to the participant will reduce the number of shares available under the 2023 Plan. If restricted shares or shares issued upon exercise of options are reacquired by the Company pursuant to a forfeiture provision, repurchase right or for any other reason, then such shares shall again become available for issuance under the 2023 Plan. Shares withheld to pay the exercise price of options or satisfy tax withholding obligations related to an award shall again become available for issuance under the 2023 Plan. Further, to the extent an award is settled in cash rather than shares, the cash settlement shall not reduce the number of shares available for issuance under the 2023 Plan.

As of September 30, 2023, 1,629,818 shares remain available for future grants under the 2023 Plan.

Certain of the employee stock options granted contain performance conditions, the vesting of which is based on a determination made by the compensation committee followed by an approval of 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. The estimated fair value of the performance awards granted and the resulting expense is based upon a certain level of achievement of the corporate objectives and other assumptions in determining fair value. The amount of expense ultimately recognized upon the grant date at completion of the performance period could change from the estimate as a result of various factors, including the level of achievement of the corporate objectives, changes in the assumptions used in the Black-Scholes model in determining fair value or fluctuations in the Company's stock price during the performance period. As of September 30, 2023, there were a total of 730,350 shares underlying performance options that were subject to vesting based on achievement of corporate objectives for 2023.

Stock Options

Options granted under the 2023 Plan and the 2013 Plan have terms of ten years from the date of grant unless earlier terminated and generally vest over a one or four year period. The exercise price of all options granted through September 30, 2023 and 2022, was equal to the fair market value of the Company's common stock on the date of grant.

A summary of stock option activity and related information as of September 30, 2023 is as follows:

	Number of Option Shares	Weighted Average Exercise Price
Outstanding at December 31, 2022	7,985,250	$ 5.55
Granted	788,683	2.39
Exercised	—	—
Cancelled	(469,184)	3.99
Outstanding at September 30, 2023	8,304,749	$ 5.34
Exercisable at September 30, 2023	7,512,231	$ 5.65

Compensation Expense

Stock-based compensation expense for stock option awards are reflected in total operating expenses for each respective period.

The following table summarizes stock-based compensation expense for the three and nine months ended September 30, 2023 and 2022, respectively:

	Three months ended September 30,		Nine months ended September 30,	
	2023	2022	2023	2022
Research, development and patents	$ 75,502	$ 53,948	$ 336,657	$ 192,819
General and administrative	143,640	104,350	611,458	321,034
Total stock-based compensation expense	$ 219,142	$ 158,298	$ 948,115	$ 513,853

The Company uses the Black-Scholes valuation model for determining the estimated fair value for stock-based awards granted to employees and considers management's current expectations of the achievement of the performance objectives for the year. The following table provides the assumptions used in the Black-Scholes valuation model used to estimate the fair value of options granted during the nine months ended September 30, 2023 and 2022, and to estimate the fair value of performance-based stock options as of September 30, 2023 and 2022.

	Nine months ended	
	September 30, 2023	September 30, 2022
Stock Option assumptions:		
Risk-free interest rate	3.59 - 4.60%	2.42 - 4.06%
Expected volatility of common stock	75.17 - 77.96%	75.13 - 79.35%
Dividend yield	0.00%	0.00%
Expected term (in years)	4.88 - 5.38	4.87 - 5.77

As of September 30, 2023, there was $0.4 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 0.3 years, on a straight-line basis. Such compensation cost will ultimately be adjusted based upon actual performance compared to the corporate objectives as described above.

The weighted-average fair value of each stock option granted during the nine months ended September 30, 2023 and 2022, estimated as of the grant date using the Black-Scholes option valuation model, was $1.60 and $1.47, respectively.

6. Stockholders' Equity

At-The-Market Issuance Sales Agreements and Private Placement Transactions

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 three and nine months ended September 30, 2023 and 2022, respectively.

7. 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 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 stock options excluded from diluted net loss per common share due to their anti-dilutive effect totaled 8,304,749 shares for both the three and nine months ended September 30, 2023 and 7,985,250 shares for both the three and nine months ended September 30, 2022.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited consolidated financial statements and notes thereto included in this Quarterly Report on Form 10-Q and the audited financial statements and notes thereto as of and for the year ended December 31, 2022 included in our Annual Report on Form 10-K, as amended, as filed with the Securities and Exchange Commission (SEC) on March 28, 2023 (Annual Report on Form 10-K, as amended). Past operating results are not necessarily indicative of results that may occur in future periods.

This Quarterly Report on Form 10-Q contains forward-looking statements that are subject to risks and uncertainties, many of which are beyond our control. Our actual results may differ from those anticipated in these forward-looking statements as a result of various factors, including those set forth in Part II of this Quarterly Report on Form 10-Q under the caption "Item 1A. Risk Factors" and under the caption "Item 1A. Risk Factors" in our Annual Report on Form 10-K, as amended. The differences may be material. Forward-looking statements discuss matters that are not historical facts. Forward-looking statements include, but are not limited to, statements regarding our plans, strategies, objectives, product development programs, clinical trials, industry, financial condition, liquidity and capital resources, future performance and other statements that are not historical facts. Such forward-looking statements include statements preceded by, followed by or that otherwise include the words "may," "might," "will," "intend," "should," "could," "can," "would," "expect," "believe," "estimate," "anticipate," "predict," "potential," "plan" or similar words. For such statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995. You should not rely unduly on these forward-looking statements, which speak only as of the date hereof. We undertake no obligation to update publicly or revise any forward-looking statements, whether as a result of new information, future events or otherwise, unless required by law.

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), prevention of acute respiratory distress syndrome, 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. As of September 30, 2023, from inception, our accumulated deficit was $413.6 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.

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.

Impact of COVID-19 and the Macroeconomic Environment on Our Business

The recent COVID-19 pandemic resulted 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 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) 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.

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

Further, the recent COVID-19 pandemic and government responses to the pandemic resulted in, and may continue to result in, downward pressure, extreme volatility, and disruptions in the capital and credit markets, reducing our ability to raise additional capital through equity, equity-linked or debt financings, which could negatively impact our short-term and long-term liquidity, access to capital markets, and our ability to operate in accordance with our operating plan, or at all.

In addition, we may be exposed to credit risk on deposits at financial institutions to the extent our account balances exceed the amount insured by the Federal Deposit Insurance Corporation. We are monitoring ongoing events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions.

Revenues

In December 2005, Avigen, Inc. and Genzyme Corporation entered into an Assignment Agreement (the “Genzyme Agreement”) in which Genzyme acquired certain gene therapy intellectual property, programs and other related assets from Avigen in exchange for an 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. We 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 us 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 products and there is no further substantive service effort required by us. In September 2023, we received notice that a gene therapy product based on AAV (adeno-associated virus) vector technology, which was covered under the Genzyme Agreement, achieved one clinical development milestone, triggering one milestone payment. Accordingly, we recognized revenue of $1.0 million during the three and nine months ended September 30, 2023.

Research, Development and Patents Expenses

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. Research, development and patents costs are expensed as incurred and we expect to increase such costs through the remainder of 2023 as our development programs progress.

The following table summarizes our research, development and patents 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):

	Three months ended September 30,		Nine months ended September 30,	
	2023	2022	2023	2022
External development expense:				
MN-221	$ 2	$ 1	$ 14	$ 402
MN-166	66	1,835	1,760	4,990
MN-001	143	116	427	158
MN-029	1	1	3	3
Other	—	—	—	11
Total external development expense	212	1,953	2,204	5,564
R&D personnel expense	412	350	1,338	1,049
R&D facility and depreciation expense	16	16	42	42
Patent expenses	93	90	263	319
Other R&D expense	62	45	160	157
Total research, development and patent expense	$ 795	$ 2,454	$ 4,007	$ 7,131

General and Administrative

Our general and administrative costs primarily consist of salaries, stock-based compensation, benefits and consulting and professional fees related to our administrative, finance, human resources, business development, legal, information systems support functions, facilities and insurance costs. General and administrative costs are expensed as incurred.

Our general and administrative expenses may increase in future periods if we are required to expand our infrastructure based on the success of our product development programs and in raising capital to support our product development programs or otherwise in connection with increased business development activities related to partnering, out-licensing or product disposition.

Critical Accounting Policies and Estimates

This discussion and analysis of our financial condition and results of operations is based on our condensed consolidated financial statements, which we have prepared in accordance with United States generally accepted accounting principles. The preparation of these condensed consolidated financial statements requires us to make estimates, judgments and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported amounts of expenses during the reporting periods. We base our estimates on historical experience and on various other factors and assumptions that we believe are reasonable under the circumstances at the time the estimates are made, the results of which form the basis for making judgments about the book values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. We periodically evaluate our estimates and judgments in light of changes in circumstances, facts and experience.

Our critical accounting policies are those accounting principles generally accepted in the United States that require us to make subjective estimates and judgments about matters that are uncertain and are likely to have a material impact on our financial condition and results of operations, as well as the specific manner in which we apply those principles. For a description of our critical accounting policies, please see the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations — Critical Accounting Policies and Use of Estimates" contained in our Annual Report on Form 10-K, as amended, for the year ended December 31, 2022. There have not been any material changes to the critical accounting policies discussed therein during the nine months ended September 30, 2023.

Results of Operations

Comparison of the three months ended September 30, 2023 and 2022

Revenues

Revenues were $1.0 million and $0.0 million for the three months ended September 30, 2023 and 2022, respectively. The increase of $1.0 million was due to the receipt of a milestone payment under the Genzyme Agreement in September 2023.

Research, Development and Patents Expenses

Research, development and patents expenses were $0.8 million and $2.5 million for the three months ended September 30, 2023 and 2022, respectively. The decrease of $1.7 million expense was primarily due to a decrease in MN-166 related manufacturing expenses and the receipt of a $0.7 million payment from the Biomedical Advanced Research and Development Authority (BARDA) to partially reimburse us for pre-clinical study costs, which was recorded as an offset to MN-166 research and development expense.

General and Administrative Expenses

General and administrative expenses were $1.4 million and $1.4 million for the three months ended September 30, 2023 and 2022, respectively. The expense was relatively the same quarter over quarter. Changes were primarily due to a decrease in legal fees offset by an increase in performance-based stock option expense.

Interest Income

Interest income was $0.4 million and $0.3 million for the three months ended September 30, 2023 and 2022, respectively. The increase of $0.1 million was 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.

Comparison of the nine months ended September 30, 2023 and 2022

Revenues

Revenues were $1.0 million and $0.0 million for the nine months ended September 30, 2023 and 2022, respectively. The increase of $1.0 million was due to the receipt of a milestone payment under the Genzyme Agreement in September 2023.

Research, Development and Patents Expenses

Research, development and patents expenses were $4.0 million and $7.1 million for the nine months ended September 30, 2023 and 2022, respectively. The decrease of $3.1 million expense was primarily due to a decrease in MN-221 and MN-166 related manufacturing expenses and receipt of a $0.7 million payment from BARDA to partially reimburse us for pre-clinical study costs, which was recorded as an offset to MN-166 research and development expense, partially offset by increased MN-001 related expenses.

General and Administrative Expenses

General and administrative expenses were $4.4 million and $4.3 million for the nine months ended September 30, 2023 and 2022, respectively. The increase of $0.1 million was primarily due to an increase in performance-based stock option expense, partially offset by lower legal fees.

Interest Income

Interest income was $1.4 million and $0.4 million for the nine months ended September 30, 2023 and 2022, respectively. The increase of $1.0 million was 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.

Other Expense

Other expense was $0.5 million and $0.1 million for the nine months ended September 30, 2023 and 2022, respectively. The increase of $0.4 million was primarily driven by penalties on early disposal of bank certificates of deposit.

Liquidity and Capital Resources

Net cash used in operating activities during the nine months ended September 30, 2023 was $6.9 million compared to $8.9 million during the same period in 2022. The $2.0 million change is primarily related to the decreased net loss and increased non-cash stock-based compensation expense, partially offset by the increase in accounts receivable of $1.0 million and changes in operating assets and liabilities for those periods.

Net cash provided by investing activities during the nine months ended September 30, 2023 was $39.9 million compared to $10.0 million used during the same period in 2022. The $49.9 million change is related to the purchase of certificates of deposits during the nine months ended September 30, 2022 and the subsequent disposal of certificates of deposit of $39.9 million during the same period in 2023.

As of September 30, 2023, we had available cash and cash equivalents of $51.5 million and working capital of $50.2 million. As of the date of this report, we believe we have working capital sufficient to fund operations at least through the end of 2024. However, we cannot provide assurance that these capital resources will be sufficient to conduct all our research and development programs as planned.

Equity Financing

On August 23, 2019, we 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 we may sell common stock through B. Riley FBR from time to time up to an aggregate offering price of $75.0 million. Sales of our 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 our prior approval. We 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 three and nine months ended September 30, 2023 and 2022.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

Not applicable.

ITEM 4. CONTROLS AND PROCEDURES.

We maintain disclosure controls and procedures that are designed to provide reasonable assurance that the information required to be disclosed in our filings under the Securities Exchange Act of 1934, as amended, or the Exchange Act, is (1) recorded, processed, summarized and reported within the time periods specified in SEC's rules and forms, and (2) accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow for timely decisions regarding required disclosure.

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. Any 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.

Evaluation of Disclosure Controls and Procedures

As required by Rule 13a-15(b) of the Exchange Act, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this report. Based on the foregoing, our Chief Executive Officer and our Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS.

We are not involved in any material legal proceedings as of September 30, 2023. We may become involved in various disputes and legal proceedings which arise in the ordinary course of business or otherwise. While it is not possible to accurately predict or determine the outcome of these matters, an adverse result in any litigation matter may occur which could harm our business.

ITEM 1A. RISK FACTORS.

In addition to the other information set forth in this report, you should carefully consider the factors discussed in Part I, “Item 1A. Risk Factors” in our Annual Report on Form 10-K, as amended, for the year ended December 31, 2022, which are incorporated herein by reference and which could materially affect our business, financial condition or future results. The risks described in our Annual Report on Form 10-K, as amended, are not the only risks facing our Company. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and/or operating results. We do not believe that there have been any material changes from the risk factors previously disclosed in our Annual Report on Form 10-K, as amended, for the year ended December 31, 2022.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS.

None

ITEM 3. DEFAULTS UPON SENIOR SECURITIES.

None

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable

ITEM 5. OTHER INFORMATION.

None

ITEM 6. EXHIBITS.

Exhibit Number	Description
3.1	Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 of the Registrant's Quarterly Report on Form 10-Q filed with the SEC on August 9, 2012 (File No. 001-33185)).
3.2	Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed with the SEC on April 25, 2019 (File No. 001-33185)).
31.1(1)	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2(1)	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1(1)*	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350 (Section 906 of the Sarbanes-Oxley Act of 2002).
32.2(1)*	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350 (Section 906 of the Sarbanes-Oxley Act of 2002).
101.INS(1)	Inline XBRL Instance Document - The instance document does not appear in the interactive data file because its XBRL tags are embedded within the inline XBRL document.
101.SCH(1)	Inline XBRL Taxonomy Extension Schema Document.
101.CAL(1)	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF(1)	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB(1)	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE(1)	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104(1)	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

(1) Filed Herewith

*

The certifications attached as Exhibit 32.1 and 32.2 that accompany this Quarterly Report on Form 10-Q are not deemed filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of MediciNova, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Quarterly Report on Form 10-Q, irrespective of any general incorporation language contained in such filing.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

MEDICINOVA, INC.

Date: November 9, 2023

By: /s/ YUICHI IWAKI

Yuichi Iwaki, M.D., Ph.D.
President and Chief Executive Officer
(on behalf of the registrant and
as the registrant's Principal Executive Officer)

By: /s/ JASON KRUGER

Jason Kruger
Chief Financial Officer
(on behalf of the registrant and
as the registrant's Principal Financial Officer)

Exhibit 31.1

MEDICINOVA, INC.

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 Quarterly Report on Form 10-Q for the quarter ended September 30, 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.

Date: November 9, 2023

By: /s/ YUICHI IWAKI

Yuichi Iwaki, M.D., Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

MEDICINOVA, INC.

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 Quarterly Report on Form 10-Q for the quarter ended September 30, 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.

Date: November 9, 2023

By: /s/ JASON KRUGER

Jason Kruger
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

Exhibit 32.1

CERTIFICATION
PURSUANT TO 18 U.S.C. SECTION 1350
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the accompanying Quarterly Report on Form 10-Q of MediciNova, Inc. (the "Company") for the quarter ended September 30, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Yuichi Iwaki, as President and Chief Executive Officer of the Company, hereby 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: November 9, 2023

By: /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. Section 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and such certification 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
PURSUANT TO 18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the accompanying Quarterly Report on Form 10-Q of MediciNova, Inc. (the "Company") for the quarter ended September 30, 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, hereby 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: November 9, 2023

By: /s/ JASON KRUGER

Jason Kruger
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. Section 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and such certification 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.