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 June 30, 2022

☐ **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 August 9, 2022, 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 has lead to 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)

	June 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 65,233,268	$ 71,430,954
Prepaid expenses and other current assets	723,736	577,992
Total current assets	65,957,004	72,008,946
Goodwill	9,600,240	9,600,240
In-process research and development	4,800,000	4,800,000
Property and equipment, net	50,472	57,565
Right-of-use asset	722,821	824,215
Other non-current assets	105,059	115,492
Total assets	$ 81,235,596	$ 87,406,458
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 642,634	$ 402,740
Accrued liabilities and other current liabilities	3,014,421	2,298,203
Operating lease liability	183,616	131,965
Total current liabilities	3,840,671	2,832,908
Deferred tax liability	201,792	201,792
Other non-current liabilities	587,404	694,674
Total liabilities	4,629,867	3,729,374
Commitments and contingencies (Note 4)		
Stockholders' equity:		
Common stock, $0.001 par value; 100,000,000 shares authorized at June 30, 2022 and December 31, 2021; 49,046,246 and 49,043,246 shares issued and outstanding at June 30, 2022 and December 31, 2021, respectively	49,046	49,043
Additional paid-in capital	477,151,484	476,788,012
Accumulated other comprehensive loss	(118,292)	(98,877)
Accumulated deficit	(400,476,509)	(393,061,094)
Total stockholders' equity	76,605,729	83,677,084
Total liabilities and stockholders' equity	$ 81,235,596	$ 87,406,458

See accompanying notes.

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

	Three months ended June 30,		Six months ended June 30,	
	2022	2021	2022	2021
Revenues	$ —	$ —	$ —	$ 4,000,000
Operating expenses:				
Research, development and patents	2,564,969	2,527,123	4,676,965	4,672,397
General and administrative	1,524,966	1,782,390	2,822,982	3,838,645
Total operating expenses	4,089,935	4,309,513	7,499,947	8,511,042
Operating loss	(4,089,935)	(4,309,513)	(7,499,947)	(4,511,042)
Interest income	91,275	34,338	128,614	71,006
Other expense	(30,338)	(8,966)	(44,082)	(31,904)
Net loss applicable to common stockholders	$ (4,028,998)	$ (4,284,141)	$ (7,415,415)	$ (4,471,940)
Basic and diluted net loss per common share	$ (0.08)	$ (0.09)	$ (0.15)	$ (0.09)
Shares used to compute basic and diluted net loss per common share	49,045,587	48,798,417	49,044,423	48,170,351
Net loss applicable to common stockholders	$ (4,028,998)	$ (4,284,141)	$ (7,415,415)	$ (4,471,940)
Other comprehensive income (loss), net of tax:				
Foreign currency translation adjustments	(11,980)	1,363	(19,415)	(5,458)
Comprehensive loss	$ (4,040,978)	$ (4,282,778)	$ (7,434,830)	$ (4,477,398)

See accompanying notes.

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

	Six Months Ended June 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

	Six Months Ended June 30, 2021					
	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	—	—	1,139,636	—	—	1,139,636
Issuance of common stock for option exercises	86,250	86	212,089	—	—	212,175
Issuance of shares under an employee stock purchase plan (ESPP)	1,424	2	6,108	—	—	6,110
Issuance of common stock in a private placement transaction, net of issuance costs	3,656,307	3,656	19,877,992	—	—	19,881,648
Net loss	—	—	—	—	(187,799)	(187,799)
Foreign currency translation adjustments	—	—	—	(6,821)	—	(6,821)
Balance at March 31, 2021	48,768,541	48,769	475,532,361	(95,040)	(383,114,641)	92,371,449
Share-based compensation	—	—	755,905	—	—	755,905
Issuance of common stock for option exercises	155,622	155	389,583	—	—	389,738
Net loss	—	—	—	—	(4,284,141)	(4,284,141)
Foreign currency translation adjustments	—	—	—	1,363	—	1,363
Balance at June 30, 2021	48,924,163	48,924	476,677,849	(93,677)	(387,398,782)	89,234,314

See accompanying notes.

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

	Six months ended June 30,	
	2022	**2021**
Operating activities:		
Net loss	$ (7,415,415)	$ (4,471,940)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash stock-based compensation	355,555	1,895,541
Depreciation and amortization	8,917	12,607
Change in carrying amount of right-of-use asset	101,394	110,527
Changes in assets and liabilities:		
Prepaid expenses and other assets	(135,311)	(439,615)
Accounts payable, accrued liabilities and other liabilities	956,112	283,692
Operating lease liabilities	(55,620)	(117,828)
Net cash used in operating activities	(6,184,368)	(2,727,016)
Investing activities:		
Acquisition of property and equipment	—	(25,794)
Net cash used in investing activities	—	(25,794)
Financing activities:		
Proceeds from issuance of common stock and exercise of common stock options	7,920	20,601,929
Common stock issuance costs	—	(118,368)
Proceeds from issuance of equity awards under ESPP	—	6,110
Net cash provided by financing activities	7,920	20,489,671
Effect of exchange rate changes on cash and cash equivalents	(21,238)	18,639
Net change in cash and cash equivalents	(6,197,686)	17,755,500
Cash and cash equivalents, beginning of period	71,430,954	60,036,763
Cash and cash equivalents, end of period	$ 65,233,268	$ 77,792,263
Supplemental disclosure of non-cash investing activities:		
Right-of-use asset obtained in exchange for operating lease liability	$ —	$ 176,416

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 JASDAQ 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, and MN-001 (tipelukast) for fibrotic and other diseases such as nonalcoholic fatty liver disease (NAFLD), nonalcoholic steatohepatitis (NASH) 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, 2021 included in the Company's 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, 2021 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.

Reclassification

Certain reclassifications have been made to the prior year financial statements to conform to the current year presentation. The reduction in carrying amount of right-of-use asset was reclassified from the change in prepaid expenses and other assets, and the change in operating lease liabilities was reclassified from the change in accounts payable, accrued liabilities and other liabilities within operating activities in the statement of cash flows for the six months ended June 30, 2021. There was no change to total net cash used in operating activities. These reclassifications had no effect on previously reported results of operations, cash flows, or retained earnings.

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.

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 $2.5 million and $2.3 million for the three months ended June 30, 2022 and 2021, respectively, and $4.5 million and $4.4 million for the six months ended June 30, 2022 and 2021, 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 and $0.2 million for the three months ended June 30, 2022 and 2021, respectively, and $0.2 million and $0.3 million for the six months ended June 30, 2022 and 2021, respectively.

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.

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. Although the pandemic resulted in a decrease in the number of patient visits at certain of the Company's clinical trial sites, the Company expects this effect to be temporary. 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 trial sites. In addition, following the outbreak of the pandemic, the Company designed and completed a clinical trial to evaluate MN-166 (ibudilast) for prevention of acute respiratory distress syndrome (ARDS) caused by COVID-19. Based on the Company's current assessment, the Company does not expect a material negative impact on its clinical development plans, long-term development timeline or liquidity due to the worldwide spread of the COVID-19 virus. However, the Company is actively monitoring this 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 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 will be effective for the Company on January 1, 2023 or at such earlier time where it is no longer a smaller reporting company. The Company is currently evaluating the potential impact that this standard may have on its consolidated financial statements and related disclosures.

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 effective for the Company on January 1, 2024 or at such earlier time where it is no longer a smaller reporting company. The Company is currently evaluating the potential impact that this standard may have on its consolidated financial statements and related disclosures.

2. Revenue Recognition

Revenue Recognition Policy

Revenues historically have consisted mainly of research and development services performed under 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.

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 it met the definition of a collaborative arrangement per Accounting Standards Codification ("ASC") 808, *Collaborative Arrangements* ("ASC 808"), which was outside 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 the two studies to be performed under the agreement represented two separate performance obligations. No services have been provided 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 June 30, 2022, the Company and Kissei were working to mutually terminate the collaboration agreement and cancel the second study contemplated thereunder and the Company expects to finalize the termination agreement in 2022.

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 $12.0 million payment. Avigen could also receive 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 March 2021, 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 clinical development milestones, triggering two milestone payments. Accordingly, the Company recognized revenue of $4 million during the six months ended June 30, 2021.

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.

Cash equivalents, including money market accounts of $0.7 million measured at fair value as of June 30, 2022 and December 31, 2021, are classified within Level 1.

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 2023 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 June 30,		Six months ended June 30,	
	2022	2021	2022	2021
Cash paid for operating lease liabilities	$ 34,283	$ 61,550	$ 68,565	$ 123,205
Operating lease costs	65,170	58,199	115,222	116,503

	June 30, 2022	December 31, 2021
Current operating lease liabilities	$ 183,616	$ 131,965
Non-current operating lease liabilities	587,404	694,674
Total operating lease liabilities	$ 771,020	$ 826,639
Weighted-average remaining lease term	4.25	4.54
Weighted-average discount rate	9.8%	9.8%

Maturities of operating lease liabilities as of June 30, 2022 were as follows:

2022	$ 127,493
2023	214,299
2024	189,170
2025	197,586
2026	206,483
Thereafter	17,269
Total minimum payments	952,300
Less imputed interest	(181,280)
Total lease liabilities	$ 771,020

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 amounts have been expended under these agreements during the three and six months ended June 30, 2022 and 2021. 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 June 30, 2022. For all other products, future potential milestone payments related to development milestones and commercialization milestones totaled $33.5 million as of June 30, 2022. 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 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 Plan is the successor to the Company's Amended and Restated 2004 Stock Incentive Plan, or 2004 Plan. A total of 8,700,000 shares of common stock are reserved for issuance under the 2013 Plan. In addition, "returning shares" that may become available from time to time are added back to the plan. "Returning shares" are shares that are subject to outstanding awards granted under the 2004 Plan that expire or terminate prior to exercise or settlement, are forfeited because of the failure to vest, are repurchased, or are withheld to satisfy tax withholding or purchase price obligations in connection with such awards. Although the Company no longer grants equity awards under the 2004 Plan, all outstanding stock awards granted 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 Plan. As of June 30, 2022, 1,920,647 shares remain available for future grants under the 2013 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.

Stock Options

Options granted under the 2013 Plan and the 2004 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 June 30, 2022 and in 2021, 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 June 30, 2022 is as follows:

	Number of Option Shares	Weighted Average Exercise Price
Outstanding at December 31, 2021	7,974,250	$ 5.81
Granted	591,700	2.28
Exercised	(3,000)	2.64
Cancelled	(549,030)	5.88
Outstanding at June 30, 2022	8,013,920	$ 5.55
Exercisable at June 30, 2022	7,389,050	$ 5.81

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 lesser 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 included in the Company's statement of operations.

For the six months ended June 30, 2021, the aggregate of 1,424 shares were issued under ESPP. No further shares will be issued under the ESPP.

Compensation Expense

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 three and six months ended June 30, 2022 and 2021, respectively:

	Three months ended June 30,		Six months ended June 30,	
	2022	2021	2022	2021
Research, development and patents	$ 96,364	$ 265,723	$ 138,871	$ 658,965
General and administrative	178,138	490,182	216,684	1,236,576
Total stock-based compensation expense	$ 274,502	$ 755,905	$ 355,555	$ 1,895,541

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 six months ended June 30, 2022 and 2021, and to estimate the fair value of performance-based stock options as of June 30, 2022 and 2021.

	Six months ended	
	June 30, 2022	June 30, 2021
Stock Option assumptions:		
Risk-free interest rate	2.42 - 3.01%	0.45 - 0.87%
Expected volatility of common stock	75.13 - 78.45%	74.31 - 76.36%
Dividend yield	0.00%	0.00%
Expected term (in years)	5.12 - 5.77	4.5 - 5.8

As of June 30, 2022, there was $0.7 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 0.75 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 six months ended June 30, 2022 and 2021, estimated as of the grant date using the Black-Scholes option valuation model, was $1.47 per option and $3.52 per option, 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 (the "2019 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 2019 ATM Agreement in the three and six months ended June 30, 2022 and 2021, respectively.

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.

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 8,013,920 shares and 8,218,265 shares for the three and six months ended June 30, 2022 and 2021, respectively.

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, 2021 included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission, or SEC, on February 16, 2022. 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. 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), and prevention of acute respiratory distress syndrome, and MN-001 (tipelukast) for fibrotic and other diseases such as nonalcoholic fatty liver disease (NAFLD), nonalcoholic steatohepatitis (NASH) 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 June 30, 2022, from inception, our accumulated deficit was $400.5 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 on Our 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 our business. Although the pandemic resulted in a decrease in the number of patient visits at certain of our clinical trial sites, we expect this effect to be temporary. We have seen an increase in the number of patient visits compared to earlier in the pandemic and we continue to enroll patients in our 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 trial sites. In addition, 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, which was based on positive results of a published study of MN-166 (ibudilast) in an animal model of ARDS. During the pandemic, we have been able to continue with routine regulatory activities. For example, we successfully submitted an Investigational New Drug Application (IND) for MN-166 (ibudilast) for prevention of ARDS which was accepted and is now open with the U.S. Food and Drug Administration (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 and that clinical trial has been completed with top-line results announced in June 2022. Based on management's current assessment, we do not expect a material negative impact on our clinical development plans, long-term development timeline or liquidity due to the worldwide spread of the COVID-19 virus. However, we are actively monitoring this situation and the possible effects on our financial condition, liquidity, operations, suppliers, industry, and workforce.

Revenues and Cost of Revenues

In October 2011, we entered into a collaboration agreement with Kissei Pharmaceutical Co., Ltd., or Kissei, to perform research and development services relating to MN-221 (bedoradrine) in exchange for a non-refundable upfront payment of $2.5 million. We assessed the services in accordance with the authoritative guidance and concluded that the two studies to be performed under the agreement represented two separate performance obligations. No services have been provided under the collaboration agreement subsequent to completion of the first study that was completed in 2013. In October 2021, we refunded $1.3 million of the prepayment. As of June 30, 2022, we and Kissei were working to mutually terminate the collaboration agreement and cancel the second study contemplated thereunder and we expect to finalize the termination agreement in 2022.

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 initial $12.0 million payment. Avigen could also receive 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 March 2021, we received notice that a gene therapy product based on AAV (adeno-associated virus) vector technology, which was covered under the Genzyme Agreement, achieved two clinical development milestones, triggering two milestone payments. Accordingly, we recognized revenue of $4 million during the six months ended June 30, 2021.

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 2022 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 June 30,		Six months ended June 30,	
	2022	2021	2022	2021
External development expense:				
MN-221	$ 399	$ 2	$ 401	$ 4
MN-166	1,538	1,739	3,155	2,988
MN-001	35	27	42	42
MN-029	1	1	2	1
Other	11	7	11	28
Total external development expense	1,984	1,776	3,611	3,063
R&D personnel expense	429	503	699	1,161
R&D facility and depreciation expense	11	12	26	24
Patent expenses	142	160	229	275
Other R&D expense (gain)	(1)	76	112	149
Total research, development and patent expense	$ 2,565	$ 2,527	$ 4,677	$ 4,672

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" contained in our Annual Report on Form 10-K for the year ended December 31, 2021. There have not been any material changes to the critical accounting policies discussed therein during the six months ended June 30, 2022.

Results of Operations

Comparison of the three months ended June 30, 2022 and 2021

Research, Development and Patents Expenses

Research, development and patents expenses were $2.6 million and $2.5 million for the three months ended June 30, 2022 and 2021, respectively. The increase of $0.1 million expense was primarily due to an increase in MN-221 related expenses, partially offset by decreases in MN-166 related expenses and a decrease in performance-based stock option expense.

General and Administrative Expenses

General and administrative expenses were $1.5 million and $1.8 million for the three months ended June 30, 2022 and 2021, respectively. The decrease of $0.3 million was primarily due to a decrease in performance-based stock option expense.

Comparison of the six months ended June 30, 2022 and 2021

Revenues

Revenues were $0.0 million and $4.0 million for the six months ended June 30, 2022 and 2021, respectively. The decrease of $4.0 million was due to the receipt of two milestone payments under the Genzyme Agreement in 2021.

Research, Development and Patents Expenses

Research, development and patents expenses were $4.7 million and $4.7 million for the six months ended June 30, 2022 and 2021, respectively. Changes were primarily due to an increase in MN-166 and MN-221 related expenses, offset by a decrease in performance-based stock option expense.

General and Administrative Expenses

General and administrative expenses were $2.8 million and $3.8 million for the six months ended June 30, 2022 and 2021, respectively. The decrease of $1.0 million was primarily due to a decrease in performance-based stock option expense.

Liquidity and Capital Resources

Net cash used in operating activities during the six months ended June 30, 2022 was $6.2 million compared to $2.7 million during the same period in 2021. The $3.5 million change is primarily related to the increased net loss, reduction in non-cash stock-based compensation, and changes in operating assets and liabilities for those periods.

Net cash provided by financing activities was $0.0 million during the six months ended June 30, 2022 compared to $20.5 million during the same period in 2021. Net cash provided by financing activities during the six months ended June 30, 2021 was primarily due to the sale of 3,656,307 shares of common stock under a Securities Purchase Agreement dated as of January 11, 2021 for net proceeds of $19.9 million. Cash proceeds from financing activities are used for working capital and general corporate purposes.

As of June 30, 2022, we had available cash and cash equivalents of $65.2 million and working capital of $62.1 million. As of the date of this report, we believe we have working capital sufficient to fund operations at least through the end of 2023. 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 (the “2019 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 2019 ATM Agreement in the three and six months ended June 30, 2022 and 2021.

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 quarter 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 June 30, 2022. 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 for the year ended December 31, 2021, 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 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 for the year ended December 31, 2021.

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, as amended (incorporated by reference to Exhibit 3.1 of the Registrant's Quarterly Report on Form 10-Q filed August 9, 2012).
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 April 25, 2019).
10.1	Lease, dated July 20, 2021, by and between the Company and The Irvine Company, LLC (incorporated by reference to Exhibit 99.1 of the Registrant's Current Report on Form 8-K filed July 23, 2021.
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

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: August 11, 2022

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 for the Period Ended June 30, 2022

I, Yuichi Iwaki, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended June 30, 2022 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: August 11, 2022

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 for the Period Ended June 30, 2022

I, Douglas Paulin, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended June 30, 2022 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: August 11, 2022

By: /s/ JASON KRUGER

Jason Kruger
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION OF
PRINCIPAL EXECUTIVE OFFICER
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 period ended June 30, 2022 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: August 11, 2022

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 OF
ACTING PRINCIPAL FINANCIAL OFFICER
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 period ended June 30, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Douglas Paulin, 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: August 11, 2022

By: /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. 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.