

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 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 March 31, 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: 001-39070

MONOPAR THERAPEUTICS INC.

(Exact name of registrant as specified in its charter)

<u>Delaware</u> (State or other jurisdiction of incorporation or organization)	<u>32-0463781</u> (I.R.S. employer identification number)
<u>1000 Skokie Blvd., Suite 350, Wilmette, IL</u> (Address of principal executive offices)	<u>60091</u> (zip code)

(847) 388-0349
(Registrant's telephone number, including area code)

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

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
<u>Common Stock, \$0.001 par value</u>	<u>MNPR</u>	<u>The Nasdaq Stock Market LLC (Nasdaq Capital Market)</u>

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

None

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 "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated Filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input checked="" type="checkbox"/>

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 Act). Yes No

The number of shares outstanding with respect to each of the classes of our common stock, as of April 30, 2022, is set forth below:

<u>Class</u>	<u>Number of shares outstanding</u>
<u>Common Stock, par value \$0.001 per share</u>	<u>12,621,592</u>

MONOPAR THERAPEUTICS INC.
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Forward-Looking Statements

This Quarterly Report on Form 10-Q contains “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended (the “Act”), and Section 21E of the Securities Exchange Act of 1934, as amended. All statements other than statements of historical facts included in this Quarterly Report on Form 10-Q are forward-looking statements. The words “hopes,” “believes,” “anticipates,” “plans,” “seeks,” “estimates,” “projects,” “expects,” “intends,” “may,” “could,” “should,” “would,” “will,” “continue,” and similar expressions are intended to identify forward-looking statements. The following uncertainties and factors, among others, could affect future performance and cause actual results to differ materially from those matters expressed in or implied by forward-looking statements:

- our ability to raise sufficient funds within the next 12 months in order for us to (1) complete the Phase 3 portion of our ongoing Validive Phase 2b/3 clinical trial and, if required, complete a second confirmatory Phase 3 clinical trial, (2) continue the clinical development of camsirubicin through and beyond our ongoing Phase 1b dose escalation clinical trial, (3) support further development of potential MNPR-101-derived radioimmunotherapeutics (RITs) and companion diagnostics to treat cancer and severe COVID-19 (patients with SARS-CoV-2 infection), and (4) support further development of MNPR-101, MNPR-202 and related compounds; as well as our ability to further raise additional funds in the future to support any future product candidate programs through completion of clinical trials, and our current and future product candidate programs through the approval processes and, if applicable, commercialization;
- our ability to find a suitable pharmaceutical partner or partners to further our development efforts, under acceptable financial terms;
- risks and uncertainties associated with our research and development activities, including our clinical trials, regulatory submissions, and manufacturing and quality activities;
- estimated timeframes for our clinical trials and regulatory reviews for approval to market products are uncertain;
- the rate of market acceptance and competitiveness in terms of pricing, efficacy and safety, of any products for which we receive marketing approval, and our ability to competitively market any such products as compared to larger pharmaceutical firms;
- the difficulties of commercialization, marketing, distribution and product manufacturing and overall strategy;
- uncertainties of intellectual property position and strategy including new discoveries and patent filings;
- our ability to attract and retain experienced and qualified key personnel and/or to find and utilize external sources of experience, expertise and scientific, medical and commercialization knowledge to complete product development and commercialization of new products;
- the risks inherent in our estimates regarding the level of needed expenses, capital requirements and the availability and timing of required additional financing at acceptable terms;
- the impact of government laws and regulations including increased governmental control of healthcare and pharmaceuticals, including direct price controls driving lower prices and other governmental regulations affecting cost requirements and structures required to deliver therapeutic products;
- the uncertain impact of the COVID-19 pandemic on our ability to advance our clinical programs and raise additional financing;

- the uncertain impact of the Russia-Ukraine conflict on our clinical material manufacturing expenses and timeline, as well as on general economic, trade and financial market conditions; and
- uncertainty of our financial and operational projections and the timelines for development of new competitive products and technologies.

Although we believe that the expectations reflected in such forward-looking statements are appropriate, we can give no assurance that such expectations will be realized. Cautionary statements are disclosed in this Quarterly Report on Form 10-Q. All subsequent written and oral forward-looking statements attributable to us or persons acting on our behalf are expressly qualified in their entirety by the cautionary statements. We undertake no obligation to update any statements made in this Quarterly Report on Form 10-Q or elsewhere, including without limitation any forward-looking statements, except as required by law.

Any forward-looking statements in this Quarterly Report on Form 10-Q reflect our current views with respect to future events or to our future financial performance and 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 these forward-looking statements. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information.

Risks Associated with Our Business

Our business is subject to numerous risks and uncertainties, including those highlighted in “Item 1A - Risk Factors” of our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 24, 2022. These risks include, among others, the following:

- We are a clinical stage biopharmaceutical company with a history of financial losses. We expect to continue to incur significant losses for the foreseeable future and may never achieve or maintain cash self-sufficiency or profitability, which could result in a decline in the market value of our common stock.
- Funds available as of April 30, 2022 are not sufficient to 1) complete the Phase 3 portion of our ongoing Validive Phase 2b/3 (“VOICE”) clinical program, including, if required, completing a second Phase 3 confirmatory clinical trial; 2) continue the clinical development of camsirubicin through and beyond our ongoing Phase 1b dose escalation clinical trial; 3) support further development of potential MNPR-101-derived radioimmunotherapeutics and companion diagnostics to treat cancer and severe COVID-19 (patients with SARS-CoV-2 infection); or 4) support continued development of MNPR-101, MNPR-202 and related compounds. If we are unable to raise enough funds within the next 12 months from the sale of our common stock or other financing efforts, or conclude a strategic agreement or collaboration such as out-licensing Validive or other product candidates, or enter into a clinical or commercial partnership, we will likely have to terminate one or more programs. There can be no assurance that we will find a suitable partner on satisfactory terms.
- We do not have and may never have any approved products on the market. Our business is highly dependent upon receiving marketing approvals from various U.S. and international governmental agencies and would be severely harmed if we are not granted approval to manufacture and sell our product candidates.
- Our clinical trials may not yield sufficiently conclusive results for regulatory agencies to approve the use of our products, which would adversely affect our financial condition.
- If we experience delays or difficulties in the enrollment of patients in clinical trials, our receipt of necessary regulatory approvals will be delayed or prevented, which would materially delay our program schedules and adversely affect our financial condition.
- We rely on well-regarded, qualified third parties to conduct our active pharmaceutical ingredient manufacturing, our drug product manufacturing, non-clinical studies, and our clinical trials. If these third parties do not or cannot successfully carry out their contractual duties and meet expected deadlines or performance goals, the initiation or conduct of our clinical trials would be delayed and we may be unable to obtain regulatory approval for, or commercialize, our current product candidates or any future products, and our financial condition would be adversely affected.
- The Russia-Ukraine conflict and resulting sanctions against Russia and Russian entities have increased fuel costs and may cause shipping delays and the broader economic, trade and financial market consequences are uncertain at this time, which may increase the cost of supplies for our clinical materials and may delay the manufacture of our clinical materials or make it more difficult or costly to raise additional financing, any of which could cause an adverse effect on our clinical programs and on our financial condition.

- We face significant competition from other biotechnology and pharmaceutical companies, and from research-based academic medical institutions in our targeted medical indications, and our operating results would be adversely affected if we fail to compete effectively. Many competitors have greater organizational capabilities in our industry, much higher available capital resources, and established marketing resources and sales in the targeted markets. Competition and technological change may make our product candidates obsolete or non-competitive.
- The termination of third-party licenses would adversely affect our rights to important compounds or technologies which are essential to market our products.
- If we and our third-party licensors do not obtain and preserve protection for our respective intellectual property rights, our competitors may be able to develop competing drugs, which would adversely affect our financial condition.
- If we lose key management leadership, and/or the expertise and experience of our scientific personnel, and if we cannot recruit qualified employees or other highly qualified and experienced personnel for future requirements, we would be at risk to experience significant program delays and increased compensation and operational costs, and our business would be materially disrupted.
- The ongoing COVID-19 pandemic could have a substantial negative impact on our business, financial condition, operating results, stock price and ability to raise additional funds.

PART I
FINANCIAL INFORMATION

Item 1. Financial Statements

Monopar Therapeutics Inc.

**Condensed Consolidated
Balance Sheets
(Unaudited)**

Assets	March 31, 2022	December 31, 2021*
Current assets:		
Cash and cash equivalents	\$ 17,819,044	\$ 20,303,869
Other current assets	193,635	217,745
Total current assets	<u>18,012,679</u>	<u>20,521,614</u>
Operating lease right-of-use asset	53,694	—
Total assets	<u>\$ 18,066,373</u>	<u>\$ 20,521,614</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable, accrued expenses and other current liabilities	\$ 1,074,124	\$ 1,580,543
Total current liabilities	1,074,124	1,580,543
Non-current operating lease liability	25,338	—
Total liabilities	<u>1,099,462</u>	<u>1,580,543</u>
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Common stock, par value of \$0.001 per share, 40,000,000 shares authorized, 12,620,592 and 12,598,125 shares issued and outstanding at March 31, 2022, and December 31, 2021, respectively	12,621	12,598
Additional paid-in capital	60,703,139	60,220,016
Accumulated other comprehensive loss	(3,744)	(3,160)
Accumulated deficit	<u>(43,745,105)</u>	<u>(41,288,383)</u>
Total stockholders' equity	16,966,911	18,941,071
Total liabilities and stockholders' equity	<u>\$ 18,066,373</u>	<u>\$ 20,521,614</u>

* Derived from the Company's audited consolidated financial statements.

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

Monopar Therapeutics Inc.
Condensed Consolidated
Statements of Operations and Comprehensive Loss
(Unaudited)

	For the Three Months Ended	
	March 31,	
	2022	2021
Operating expenses:		
Research and development	\$ 1,677,932	\$ 1,206,779
General and administrative	779,254	687,936
Total operating expenses	<u>2,457,186</u>	<u>1,894,715</u>
Loss from operations	(2,457,186)	(1,894,715)
Other income:		
Interest income	464	10,696
Net loss	<u>(2,456,722)</u>	<u>(1,884,019)</u>
Other comprehensive income (loss):		
Foreign currency translation gain (loss)	(584)	2,774
Comprehensive loss	<u>\$ (2,457,306)</u>	<u>\$ (1,881,245)</u>
Net loss per share:		
Basic and diluted	<u>\$ (0.19)</u>	<u>\$ (0.16)</u>
Weighted average shares outstanding:		
Basic and diluted	<u>12,604,443</u>	<u>12,139,422</u>

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

Monopar Therapeutics Inc.**Condensed Consolidated Statements of Stockholders' Equity**
Three Months Ended March 31, 2022
(Unaudited)

	<u>Common Stock</u>		<u>Additional Paid- in Capital</u>	<u>Accumulated Other Comprehensive Income (Loss)</u>	<u>Accumulated Deficit</u>	<u>Total Stockholders' Equity</u>
	<u>Shares</u>	<u>Amount</u>				
Balance at January 1, 2022	12,598,125	\$ 12,598	\$ 60,220,016	\$ (3,160)	\$ (41,288,383)	\$ 18,941,071
Issuance of common stock to non-employee directors pursuant to vested restricted stock units	11,436	12	(12)	—	—	—
Issuance of common stock to employees pursuant to vested restricted stock units, net of taxes	11,031	11	(16,677)	—	—	(16,666)
Stock-based compensation (non-cash)	—	—	499,812	—	—	499,812
Net loss	—	—	—	—	(2,456,722)	(2,456,722)
Other comprehensive loss	—	—	—	(584)	—	(584)
Balance at March 31, 2022	<u>12,620,592</u>	<u>\$ 12,621</u>	<u>\$ 60,703,139</u>	<u>\$ (3,744)</u>	<u>\$ (43,745,105)</u>	<u>\$ 16,966,911</u>

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

Monopar Therapeutics Inc.

Condensed Consolidated Statements of Stockholders' Equity (continued)
Three Months Ended March 31, 2021
(Unaudited)

	<u>Common Stock</u>		<u>Additional Paid- in Capital</u>	<u>Accumulated Other Comprehensive Income (Loss)</u>	<u>Accumulated Deficit</u>	<u>Total Stockholders' Equity</u>
	<u>Shares</u>	<u>Amount</u>				
Balance at January 1, 2021	11,453,465	\$ 11,453	\$ 47,873,570	\$ (7,873)	\$ (32,185,159)	\$ 15,691,991
Issuance of common stock under a Capital on Demand™ Sales Agreement with JonesTrading Institutional Services LLC, net of commissions and fees of \$338,153	1,104,047	1,104	10,924,208	—	—	10,925,312
Issuance of common stock to non-employee directors pursuant to vested restricted stock units	3,004	3	(3)	—	—	—
Issuance of common stock to employees pursuant to vested restricted stock units, net of taxes	6,504	7	(21,507)	—	—	(21,500)
Issuance of common stock upon exercise of stock options	2,913	3	17,475	—	—	17,478
Stock-based compensation (non-cash)	—	—	368,232	—	—	368,232
Net loss	—	—	—	—	(1,884,019)	(1,884,019)
Other comprehensive income	—	—	—	2,774	—	2,774
Balance at March 31, 2021	<u>12,569,933</u>	<u>\$ 12,570</u>	<u>\$ 59,161,975</u>	<u>\$ (5,099)</u>	<u>\$ (34,069,178)</u>	<u>\$ 25,100,268</u>

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

Monopar Therapeutics Inc.

**Condensed Consolidated
Statements of Cash Flows
(Unaudited)**

	For the Three Months Ended March 31,	
	2022	2021
Cash flows from operating activities:		
Net loss	\$ (2,456,722)	\$ (1,884,019)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense (non-cash)	499,812	368,232
Changes in operating assets and liabilities, net		
Other current assets	(24,110)	51,879
Accounts payable, accrued expenses and other current liabilities	(532,321)	(370,394)
Operating lease right-of-use assets and liabilities, net	2,379	—
Net cash used in operating activities	<u>(2,467,500)</u>	<u>(1,938,060)</u>
Cash flows from financing activities:		
Cash proceeds from the sales of common stock under a Capital on Demand TM Sales Agreement with JonesTrading Institutional Services LLC, net of commissions, fees and offering costs of \$338,153	—	10,925,312
Taxes paid related to net share settlement of vested restricted stock units	(16,666)	(21,500)
Cash proceeds from the issuance of stock upon exercise of stock options	—	17,478
Net cash provided by (used in) financing activities	<u>(16,666)</u>	<u>10,921,290</u>
Effect of exchange rates	(659)	2,774
Net increase (decrease) in cash and cash equivalents	<u>(2,484,825)</u>	<u>8,986,004</u>
Cash and cash equivalents at beginning of period	<u>20,303,869</u>	<u>16,737,109</u>
Cash and cash equivalents at end of period	<u>\$ 17,819,044</u>	<u>\$ 25,723,113</u>
Supplemental cash flow information:		
Cash paid for amounts included in the measurement of operating lease liability	\$ 2,379	—
Supplemental non-cash flow information:		
Lease liability arising out of obtaining right-of-use asset	\$ 53,694	—

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

MONOPAR THERAPEUTICS INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

March 31, 2022

Note 1 - Nature of Business and Liquidity

Nature of Business

Monopar Therapeutics Inc. (“Monopar” or the “Company”) is a clinical-stage biopharmaceutical company focused on developing proprietary therapeutics designed to extend life or improve quality of life for cancer patients. Monopar currently has four compounds in development: 1) Validive[®] (clonidine hydrochloride mucobuccal tablet; clonidine HCl MBT), a Phase 2b/3 clinical stage, first-in-class mucoadhesive buccal tablet for the prevention of radiation induced severe oral mucositis (“SOM”) in oropharyngeal cancer patients; 2) camsirubicin (generic name for MNPR-201, GPX-150; 5-imino-13-deoxydoxorubicin), a Phase 1b clinical stage novel analog of doxorubicin engineered specifically to retain anticancer activity while minimizing toxic effects on the heart; 3) MNPR-101, a preclinical stage uPAR-targeted antibody being developed as a radioimmunotherapeutic and companion diagnostic for advanced cancers and severe COVID-19; and 4) an early stage camsirubicin analog, MNPR-202, for various cancers.

Liquidity

The Company has incurred an accumulated deficit of approximately \$43.7 million as of March 31, 2022. To date, the Company has primarily funded its operations with the net proceeds from the Company’s initial public offering of its common stock on Nasdaq, sales of its common stock in the public market through an at-the-market sales agreement, private placements of convertible preferred stock and of common stock and cash provided in the camsirubicin asset purchase transaction. Management estimates that currently available cash will provide sufficient funds to enable the Company to meet its obligations at least through June 2023. The Company’s ability to fund its future operations, including the continued clinical development of Validive and camsirubicin, is dependent upon its ability to execute its business strategy, to obtain additional funding and/or to execute collaborative research agreements. There can be no certainty that future financing or collaborative research agreements will occur in the amounts required or at a time needed to maintain operations, if at all.

The coronavirus disease (“COVID-19”) pandemic continues to affect economies and business around the world. In response to COVID-19 and its effects on clinical trials, in 2020 Monopar modified the original adaptive design Phase 3 clinical trial for its lead product candidate, Validive, to be a Phase 2b/3 clinical trial (“VOICE”) to better fit the types of trials which can enroll sufficient required patients in the current environment. This modification allowed the Company to activate the VOICE clinical trial without requiring near-term financing. To complete the VOICE clinical program, including, if required, completing a second Phase 3 confirmatory clinical trial, Monopar will require additional funding in the millions or tens of millions of dollars (depending on if the Company has consummated a collaboration or partnership or neither for Validive), which it is planning to pursue within the next 12 months. Due to many uncertainties, the Company is unable to estimate the pandemic’s financial impact or duration in light of global vaccine rollouts and adverse new cases surging from COVID-19 variants at this time, or its potential impact on the Company’s current clinical trials, including COVID-19’s effect on drug candidate manufacturing, shipping, patient recruitment at clinical sites and regulatory agencies around the globe.

The Russia-Ukraine conflict and resulting sanctions against Russia and Russian entities have increased fuel costs and may cause shipping delays and the broader economic, trade and financial market consequences are uncertain at this time, which may increase the cost of supplies for the Company’s clinical materials and may delay the manufacture of its clinical materials or make it more difficult or costly to raise additional financing, any of which could cause an adverse effect on the Company’s clinical programs and on the Company’s financial condition.

MONOPAR THERAPEUTICS INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

March 31, 2022

Note 2 - Significant Accounting Policies

Basis of Presentation

These condensed consolidated financial statements include the financial results of Monopar Therapeutics Inc., its wholly-owned French subsidiary, Monopar Therapeutics, SARL, and its wholly-owned Australian subsidiary, Monopar Therapeutics Australia Pty Ltd and have been prepared in accordance with accounting principles generally accepted in the U.S. (“GAAP”) and include all disclosures required by GAAP for financial reporting. All intercompany accounts have been eliminated. The principal accounting policies applied in the preparation of these condensed consolidated financial statements are set out below and have been consistently applied in all periods presented. The Company has been primarily involved in performing research activities, developing product candidates, and raising capital to support and expand these activities.

The accompanying unaudited condensed consolidated financial statements contain all normal, recurring adjustments necessary to present fairly the Company’s condensed consolidated financial position as of March 31, 2022, and the Company’s condensed consolidated results of operations and comprehensive loss and the Company’s condensed consolidated cash flows for the three months ended March 31, 2022, and 2021.

The condensed consolidated results of operations and comprehensive loss and condensed consolidated cash flows for the periods presented are not necessarily indicative of the consolidated results of operations or cash flows which may be reported for the remainder of 2022 or for any future period. Certain information and footnote disclosures normally included in financial statements prepared in accordance with GAAP have been condensed or omitted. The accompanying unaudited interim condensed consolidated financial statements should be read in conjunction with the audited 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 U.S. Securities and Exchange Commission (the “SEC”) on March 24, 2022.

Functional Currency

The Company’s consolidated functional currency is the U.S. Dollar. The Company’s Australian subsidiary and French subsidiary use the Australian Dollar and European Euro, respectively, as their functional currency. At each quarter-end, each foreign subsidiary’s balance sheets are translated into U.S. Dollars based upon the quarter-end exchange rate, while their statements of operations and comprehensive loss and statements of cash flows are translated into U.S. Dollars based upon an average exchange rate during the period.

Comprehensive Loss

Comprehensive loss represents net loss plus any gains or losses such as foreign currency translations gains and losses that are typically reflected on the Company’s condensed consolidated statements of stockholders’ equity.

Use of Estimates

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

MONOPAR THERAPEUTICS INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

March 31, 2022

Going Concern Assessment

The Company applies Accounting Standards Codification 205-40 (“ASC 205-40”), *Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern*, which the Financial Accounting Standards Board (“FASB”) issued to provide guidance on determining when and how reporting companies must disclose going concern uncertainties in their financial statements. ASC 205-40 requires management to perform interim and annual assessments of an entity’s ability to continue as a going concern within one year of the date of issuance of the entity’s financial statements (or within one year after the date on which the financial statements are available to be issued, when applicable). Further, a company must provide certain disclosures if there is “substantial doubt about the entity’s ability to continue as a going concern.” In April 2022, the Company analyzed its cash requirements at least through June 2023 and has determined that, based upon the Company’s current available cash, the Company has no substantial doubt about its ability to continue as a going concern.

Cash Equivalents

The Company considers all highly liquid investments purchased with a maturity of 90 days or less on the date of purchase to be cash equivalents. Cash equivalents as of March 31, 2022, and December 31 2021, consisted of one money market account.

Prepaid Expenses

Prepayments are expenditures for goods or services before the goods are used or the services are received and are charged to operations as the benefits are realized. Prepaid expenses may include payments to development collaborators in excess of actual expenses incurred by the collaborator measured at the end of each reporting period. Prepayments also include insurance premiums, dues and subscriptions and software costs of \$10,000 or more per year that are expensed monthly over the life of the contract, which is typically one year. Prepaid expenses are reflected on the Company’s condensed consolidated balance sheets as other current assets.

Leases

Lease agreements are evaluated to determine whether an arrangement is or contains a lease in accordance with ASC 842, *Leases*. Right-of-use lease assets and lease liabilities are recognized based on the present value of the future minimum lease payments over the lease term at the commencement date. The right-of-use lease asset includes any lease payments made and excludes lease incentives. The incremental borrowing taking into consideration with the Company’s credit quality and borrowing rate for similar assets is used in determining the present value of future payments. Lease expense is recorded as general and administrative expenses on the Company’s condensed consolidated statements of operations and comprehensive loss.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentration of credit risk consist of cash and cash equivalents. The Company maintains cash and cash equivalents at two reputable financial institutions. As of March 31, 2022, the balance at one financial institution was in excess of the \$250,000 Federal Deposit Insurance Corporation (“FDIC”) insurable limit. The Company has not experienced any losses on its deposits since inception and management believes the Company is not exposed to significant risks with respect to these financial institutions.

MONOPAR THERAPEUTICS INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

March 31, 2022

Fair Value of Financial Instruments

For financial instruments consisting of cash and cash equivalents, accounts payable, accrued expenses, and other current liabilities, the carrying amounts are reasonable estimates of fair value due to their relatively short maturities.

The Company adopted ASC 820, *Fair Value Measurements and Disclosures*, as amended, which addresses the measurement of the fair value of financial assets and financial liabilities. Under this standard, fair value is defined as the price that would be received to sell an asset or paid to transfer a liability (i.e., the “exit price”) in an orderly transaction between market participants at the measurement date.

The standard establishes a hierarchy for inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the most observable inputs be used when available. Observable inputs reflect assumptions market participants would use in pricing an asset or liability based on market data obtained from independent sources. Unobservable inputs reflect a reporting entity’s pricing an asset or liability developed based on the best information available under the circumstances. The fair value hierarchy consists of the following three levels:

Level 1 - instrument valuations are obtained from real-time quotes for transactions in active exchange markets involving identical assets.

Level 2 - instrument valuations are obtained from readily available pricing sources for comparable instruments.

Level 3 - instrument valuations are obtained without observable market values and require a high-level of judgment to determine the fair value.

Determining which category an asset or liability falls within the hierarchy requires significant judgment. The Company evaluates its hierarchy disclosures each reporting period. There were no transfers between Level 1, 2 or 3 of the fair value hierarchy during the three months ended March 31, 2022, and 2021. The following table presents the assets and liabilities recorded that are reported at fair value on our condensed consolidated balance sheets on a recurring basis. No values were recorded in Level 2 or Level 3 at March 31, 2022, and December 31, 2021.

Assets and Liabilities Measured at Fair Value on a Recurring Basis

March 31, 2022	Level 1	Total
Assets		
Cash equivalents ⁽¹⁾	\$ 17,599,669	\$ 17,599,669
Total	<u>\$ 17,599,669</u>	<u>\$ 17,599,669</u>
December 31, 2021	Level 1	Total
Assets		
Cash equivalents ⁽¹⁾	\$ 20,014,205	\$ 20,014,205
Total	<u>\$ 20,014,205</u>	<u>\$ 20,014,205</u>

(1) Cash equivalents represent the fair value of the Company’s investment in a money market account.

MONOPAR THERAPEUTICS INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

March 31, 2022

Net Loss per Share

Net loss per share for the three months ended March 31, 2022, and 2021, is calculated by dividing net loss by the weighted-average shares of common stock outstanding during the period. Diluted net loss per share for the three months ended March 31, 2022, and 2021, is calculated by dividing net loss by the weighted-average shares of the sum of a) weighted average common stock outstanding (12,604,443 and 12,139,422 shares for the three months ended March 31, 2022, and 2021, respectively) and b) potentially dilutive shares of common stock (such as stock options and restricted stock units) outstanding during the period. As of March 31, 2022, and 2021, potentially dilutive securities included stock-based awards to purchase up to 2,548,155 and 1,600,215 shares of the Company's common stock, respectively. For the three months ended March 31, 2022, and 2021, potentially dilutive securities are excluded from the computation of fully diluted net loss per share as their effect is anti-dilutive.

Research and Development Expenses

Research and development ("R&D") costs are expensed as incurred. Major components of R&D expenses include salaries and benefits paid to the Company's R&D staff, compensation expenses of G&A personnel performing R&D, fees paid to consultants and to the entities that conduct certain R&D activities on the Company's behalf and materials and supplies which were used in R&D activities during the reporting period.

Clinical Trials Accruals

The Company accrues and expenses the costs for clinical trial activities performed by third parties based upon estimates of the percentage of work completed over the life of the individual study in accordance with agreements established with contract research organizations, service providers, and clinical trial sites. The Company estimates the amounts to accrue based upon discussions with internal clinical personnel and external service providers as to progress or stage of completion of trials or services and the agreed upon fee to be paid for such services. Costs of setting up clinical trial sites for participation in the trials are expensed immediately as R&D expenses. Clinical trial site costs related to patient screening and enrollment are accrued as patients are screened/entered into the trial.

Collaborative Agreements

The Company and its collaborative partners are active participants in collaborative agreements and all parties would be exposed to significant risks and rewards depending on the technical and commercial success of the activities. Contractual payments to the other parties in collaboration agreements and costs incurred by the Company when the Company is deemed to be the principal participant for a given transaction are recognized on a gross basis in R&D expenses. Royalties and license payments are recorded as earned.

During the three months ended March 31, 2022, and 2021, no milestones were met, and no royalties were earned, therefore, the Company did not pay or accrue/expense any license or royalty payments.

MONOPAR THERAPEUTICS INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

March 31, 2022

Licensing Agreements

The Company has various agreements licensing technology utilized in the development of its product or technology programs. The licenses contain success milestone obligations and royalties on future sales. During the three months ended March 31, 2022, and 2021, no milestones were met, and no royalties were earned, therefore, the Company did not pay or accrue/expense any license or royalty payments under any of its license agreements.

Patent Costs

The Company expenses costs relating to issued patents and patent applications, including costs relating to legal, renewal and application fees, as a component of general and administrative expenses in its condensed consolidated statements of operations and comprehensive loss.

Income Taxes

The Company uses an asset and liability approach for accounting for deferred income taxes, which requires recognition of deferred income tax assets and liabilities for the expected future tax consequences of events that have been recognized in its financial statements but have not been reflected in its taxable income. Estimates and judgments are required in the calculation of certain tax liabilities and in the determination of the recoverability of certain deferred income tax assets, which arise from temporary differences and carryforwards. Deferred income tax assets and liabilities are measured using the currently enacted tax rates that apply to taxable income in effect for the years in which those tax assets and liabilities are expected to be realized or settled.

The Company regularly assesses the likelihood that its deferred income tax assets will be realized from recoverable income taxes or recovered from future taxable income. To the extent that the Company believes any amounts are not “more likely than not” to be realized, the Company records a valuation allowance to reduce the deferred income tax assets. In the event the Company determines that all or part of the net deferred tax assets are not realizable in the future, an adjustment to the valuation allowance would be charged to earnings in the period such determination is made. Similarly, if the Company subsequently determines deferred income tax assets that were previously determined to be unrealizable are now realizable, the respective valuation allowance would be reversed, resulting in an adjustment to earnings in the period such determination is made.

Internal Revenue Code Sections 382 and 383 (“Sections 382 and 383”) limit the use of net operating loss (“NOL”) carryforwards and R&D credits, after an ownership change. To date, the Company has not conducted a Section 382 or 383 study, however, because the Company will continue to raise significant amounts of equity in the coming years, the Company expects that Sections 382 and 383 will limit the Company’s usage of NOLs and R&D credits in the future.

MONOPAR THERAPEUTICS INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

March 31, 2022

ASC 740, *Income Taxes*, requires that the tax benefit of net operating losses, temporary differences, and credit carryforwards be recorded as an asset to the extent that management assesses that realization is “more likely than not.” Realization of the future tax benefits is dependent on the Company’s ability to generate sufficient taxable income within the carryforward period. The Company has reviewed the positive and negative evidence relating to the realizability of the deferred tax assets and has concluded that the deferred tax assets are not “more likely than not” to be realized. As a result, the Company recorded a full valuation allowance as of March 31, 2022, and December 31 2021. U.S. Federal R&D tax credits from 2016 to 2019 were utilized to reduce payroll taxes in future periods and were recorded as other current assets (anticipated to be received within 12 months), on the Company’s condensed consolidated balance sheets. The Company intends to maintain the valuation allowance until sufficient evidence exists to support its reversal. The Company regularly reviews its tax positions. For a tax benefit to be recognized, the related tax position must be “more likely than not” to be sustained upon examination. Any amount recognized is generally the largest benefit that is “more likely than not” to be realized upon settlement. The Company’s policy is to recognize interest and penalties related to income tax matters as an income tax expense. For the three months ended March 31, 2022, and 2021, the Company did not have any interest or penalties associated with unrecognized tax benefits.

The Company is subject to U.S. Federal, Illinois and California state income taxes. In addition, the Company is subject to local tax laws of France and Australia. Tax regulations within each jurisdiction are subject to the interpretation of the related tax laws and regulations and require significant judgment to apply. Monopar was originally formed as an LLC in December 2014, then incorporated on December 16, 2015. The Company is subject to U.S. Federal, state and local tax examinations by tax authorities for the tax years 2015 through 2021. The Company does not anticipate significant changes to its current uncertain tax positions through March 31, 2022. The Company plans on filing its U.S. Federal and state tax returns for the year ended December 31, 2021, prior to the extended filing deadlines in all jurisdictions.

Stock-Based Compensation

The Company accounts for stock-based compensation arrangements with employees, non-employee directors and consultants using a fair value method, which requires the recognition of compensation expense for costs related to all stock-based awards, including stock option and restricted stock unit (“RSU”) grants. The fair value method requires the Company to estimate the fair value of stock-based payment awards on the date of grant using an option pricing model or the closing stock price on the date of grant in the case of RSUs.

Stock-based compensation expense for awards granted to employees, non-employee directors and consultants are based on the fair value of the underlying instrument calculated using the Black-Scholes option-pricing model on the date of grant for stock options and using the closing stock price on the date of grant for RSUs and recognized as expense on a straight-line basis over the requisite service period, which is the vesting period. Determining the appropriate fair value model and related assumptions requires judgment, including estimating the future stock price volatility and expected terms. The expected volatility rates are estimated based on the Company’s actual historical volatility over the two-year period from its initial public offering on December 18, 2019 through December 31, 2021. The expected term for options granted to date is estimated using the simplified method. Forfeitures only include known forfeitures to-date as the Company accounts for forfeitures as they occur due to a limited history of forfeitures. The Company has not paid dividends and does not anticipate paying a cash dividend in the future vesting period and, accordingly, uses an expected dividend yield of zero. The risk-free interest rate is based on the rate of U.S. Treasury securities with maturities consistent with the estimated expected term of the awards.

MONOPAR THERAPEUTICS INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

March 31, 2022

Note 3 - Capital Stock

Holders of the common stock are entitled to receive such dividends as may be declared by the Board of Directors out of funds legally available therefor. To date no dividends have been declared. Upon dissolution and liquidation of the Company, holders of the common stock are entitled to a ratable share of the net assets of the Company remaining after payments to creditors of the Company. The holders of shares of common stock are entitled to one vote per share for the election of each director nominated to the Board and one vote per share on all other matters submitted to a vote of stockholders.

The Company's amended and restated certificate of incorporation authorizes the Company to issue 40,000,000 shares of common stock with a par value of \$0.001 per share.

Sales of Common Stock

On January 13, 2020, the Company entered into a Capital on Demand™ Sales Agreement with JonesTrading Institutional Services LLC ("JonesTrading"), as sales agent, pursuant to which Monopar could offer and sell (at its discretion), from time to time, through or to JonesTrading shares of Monopar's common stock, having an aggregate offering price of up to \$19.7 million. Pursuant to this agreement, during the three months ended March 31, 2021, the Company sold 1,104,047 shares of its common stock at an average gross price per share of \$10.20 for net proceeds of \$10,925,312 after fees and commissions of \$338,153. During the three months ended March 31, 2022, the Company did not sell any shares of common stock as the maximum aggregate offering price under the agreement was reached during the first quarter of 2021. The Company does not expect further sales under this agreement; however, subsequent to March 31, 2022, the Company entered into a new agreement with JonesTrading. See Note 7 – Subsequent Events.

As of March 31, 2022, the Company had 12,620,592 shares of common stock issued and outstanding.

Note 4 - Stock Incentive Plan

In April 2016, the Company's Board of Directors and stockholders representing a majority of the Company's outstanding stock at that time, approved the Monopar Therapeutics Inc. 2016 Stock Incentive Plan, as amended (the "Plan"), allowing the Company to grant up to an aggregate 700,000 shares of stock-based awards in the form of stock options, restricted stock units, stock appreciation rights and other stock-based awards to employees, non-employee directors and consultants. In October 2017, the Company's Board of Directors voted to increase the stock award pool to 1,600,000 shares of common stock, which subsequently was approved by the Company's stockholders. In April 2020, the Company's Board of Directors voted to increase the stock award pool to 3,100,000 (an increase of 1,500,000 shares of common stock), which was approved by the Company's stockholders in June 2020. In April 2021, the Company's Board of Directors voted to approve an amendment to the 2016 Stock Incentive Plan to remove certain individual award limits and other provisions related to I.R.C. Section 162(m) and to update the limit on Incentive Stock Options to no more than 100% of the maximum aggregate number of shares which may be granted under the plan, which was approved by the Company's stockholders in June 2021.

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NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

March 31, 2022

During the three months ended March 31, 2022, the Company's Plan Administrator Committee (with regards to non-officer employees and consultants) and the Company's Compensation Committee, as ratified by the Board of Directors (in the case of executive officers and non-employee directors), granted to executive officers, non-officer employees, non-employee directors and a consultant aggregate stock options for the purchase of 553,064 shares of the Company's common stock with exercise prices ranging from \$2.50 to \$3.52 per share which vest over 1 to 4 years. All stock option grants have a 10-year term. In addition, during the three months ended March 31, 2022, an aggregate 403,522 restricted stock units were granted to executive officers, non-officer employees and non-employee directors which vest over 1 to 4 years.

Under the Plan, the per share exercise price for the shares to be issued upon exercise of an option shall be determined by the Plan Administrator, except that the per share exercise price shall be no less than 100% of the fair market value per share on the grant date. Fair market value is the Company's closing price on the grant date on Nasdaq. Stock options generally expire after 10 years.

Stock option activity under the Plan was as follows:

	Options Outstanding	
	Number of Shares Subject to Options	Weighted-Average Exercise Price
Balances at December 31, 2021	1,543,989	4.78
Granted ⁽¹⁾	553,064	2.81
Forfeited ⁽²⁾	(31,950)	8.17
Balances at March 31, 2022	2,065,103	4.20
Unvested options outstanding expected to vest ⁽³⁾	808,621	4.27

(1) 553,064 options vest as follows: options to purchase 482,552 shares of the Company's common stock vest 6/48ths on the six-month anniversary of grant date and 1/48th per month thereafter; options to purchase 60,512 shares of the Company's common stock vest quarterly over one year; and options to purchase 10,000 shares of the Company's common stock vest monthly over one year. Exercise prices range from \$2.50 to \$3.52 per share.

(2) Forfeited options represent unvested shares and vested, expired shares related to employee terminations.

(3) Forfeitures only include known forfeitures to-date as the Company accounts for forfeitures as they occur due to a limited history of forfeitures.

MONOPAR THERAPEUTICS INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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A summary of options outstanding as of March 31, 2022, is shown below:

Exercise Prices	Number of Shares Subject to Options Outstanding	Weighted-Average Remaining Contractual Term in Years	Number of Shares Subject to Options Fully Vested and Exercisable	Weighted-Average Remaining Contractual Term in Years
\$0.001-\$5.00	1,119,651	7.17	574,809	4.63
\$5.01-\$10.00	794,095	7.12	561,831	6.61
\$10.01-\$15.00	145,232	7.84	113,717	7.84
\$15.01-\$20.00	6,125	7.84	6,125	7.84
	2,065,103		1,256,482	

Restricted stock unit activity under the Plan was as follows:

	Restricted Stock Units	Weighted-Average Grant Date Fair Value per Unit
Unvested balance at December 31, 2021	111,462	8.44
Granted	403,522	2.80
Vested	(28,096)	7.33
Forfeited	(3,836)	3.39
Unvested Balance at March 31, 2022	483,052	3.83

During the three months ended March 31, 2022, and 2021, the Company recognized \$204,474 and \$144,048 of employee, non-employee director and consultant stock-based compensation expense as general and administrative expenses, respectively, and \$295,338 and \$224,184 as research and development expenses, respectively. The stock-based compensation expense is allocated on a departmental basis, based on the classification of the stock-based award holder. No income tax benefits have been recognized in the consolidated statements of operations and comprehensive loss for stock-based compensation arrangements.

The fair value of options granted from inception to March 31, 2022, was based on the Black-Scholes option-pricing model assuming the following factors: 4.7 to 6.2 years expected term, 55% to 91.6% volatility, 0.4% to 2.9% risk free interest rate and zero dividends. The expected term for options granted to date was estimated using the simplified method.

MONOPAR THERAPEUTICS INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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	Three Months Ended March	
	31,	
	2022	2021
Stock options granted	553,064	196,476
Weighted-average grant date fair value per share	\$ 2.11	\$ 4.90
Fair value of shares vested	\$ 292,328	\$ 255,624

At March 31, 2022, the aggregate intrinsic value of outstanding vested stock options was approximately \$1.4 million (unvested stock options had \$200 in intrinsic value) and the weighted-average exercise price in aggregate was \$4.20 which includes \$4.16 for fully vested stock options and \$4.27 for stock options expected to vest. At March 31, 2022, unamortized unvested balance of stock-based compensation was \$4.1 million, to be amortized over the following 2.9 years.

Note 5 - Related Party Transactions

As of March 31, 2022, Tactic Pharma, LLC (“Tactic Pharma”), the Company’s initial investor, beneficially owned 34% of Monopar’s common stock and during the three months ended March 31, 2022, there were no transactions between Tactic Pharma and Monopar.

None of the related parties discussed in this paragraph received compensation other than market-based salary, market-based stock-based compensation and benefits and performance-based incentive bonus or in the case of non-employee directors, market-rate board fees and market-rate stock-based compensation. The Company considers the following individuals as related parties: Three of the Company’s board members were also Managing Members of Tactic Pharma as of March 31, 2022. Chandler D. Robinson is a Company Co-Founder, Chief Executive Officer, common stockholder, Managing Member of Tactic Pharma, former Manager of the predecessor LLC, Manager of CDR Pharma, LLC and board member of Monopar as a C Corporation. Andrew P. Mazar a Company Co-Founder, former Executive Vice President of Research and Development and Chief Scientific Officer, current common stockholder, current Managing Member of Tactic Pharma, former Manager of the predecessor LLC and former board member of Monopar as a C Corporation. Dr. Mazar resigned from his employment and board positions effective April 8, 2022. Michael Brown is a Managing Member of Tactic Pharma (as of February 1, 2019, with no voting power as it relates to Monopar), a previous managing member of Monopar as an LLC, common stockholder and Board member of Monopar as a C Corporation.

Note 6 – Commitments and Contingencies

License, Development and Collaboration Agreements

Onxeo S.A.

In June 2016, the Company executed an option and license agreement with Onxeo S.A. (“Onxeo”), a public French company, which gave Monopar the exclusive option to license (on a world-wide exclusive basis) Validive to pursue treating severe oral mucositis in patients undergoing chemoradiation treatment for head and neck cancers. The pre-negotiated Onxeo license agreement for Validive as part of the option agreement includes clinical, regulatory, developmental and sales milestones that could reach up to \$108 million if the Company achieves all milestones, and escalating royalties on net sales from 5% to 10%. On September 8, 2017, the Company exercised the license option, and therefore paid Onxeo the \$1 million fee under the option and license agreement.

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Under the agreement, the Company is required to pay royalties to Onxeo on a product-by-product and country-by-country basis until the later of (1) the date when a given product is no longer within the scope of a patent claim in the country of sale or manufacture, (2) the expiry of any extended exclusivity period in the relevant country (such as orphan drug exclusivity, pediatric exclusivity, new chemical entity exclusivity, or other exclusivity granted beyond the expiry of the relevant patent), or (3) a specific time period after the first commercial sale of the product in such country. In most countries, including the U.S., the patent term is generally 20 years from the earliest claimed filing date of a non-provisional patent application in the applicable country, not taking into consideration any potential patent term adjustment that may be filed in the future or any regulatory extensions that may be obtained. The royalty termination provision pursuant to (3) described above is shorter than 20 years and is the least likely cause of termination of royalty payments.

The Onxeo license agreement does not have a pre-determined term, but expires on a product-by-product and country-by-country basis; that is, the agreement expires with respect to a given product in a given country whenever the Company's royalty payment obligations with respect to such product have expired. The agreement may also be terminated early for cause if either the Company or Onxeo materially breach the agreement, or if either the Company or Onxeo become insolvent. The Company may also choose to terminate the agreement, either in its entirety or as to a certain product and a certain country, by providing Onxeo with advance notice.

The Company is internally developing Validive and has its ongoing VOICE clinical trial, which, if successful, may allow the Company to apply for marketing approval within the next several years. The Company will need to raise significant funds or enter into a collaboration partnership to support the further development, including potential commercialization of Validive. As of March 31, 2022, the Company had not reached any of the pre-specified milestones and has not been required to pay Onxeo any funds under this license agreement other than the \$1 million one-time license fee.

Grupo Español de Investigación en Sarcomas ("GEIS")

In June 2019, the Company executed a clinical collaboration agreement with GEIS for the development of camsirubicin in patients with advanced soft tissue sarcoma ("ASTS"). Following completion of the Phase 1b clinical trial in the U.S. that Monopar initiated in the third quarter of 2021 with the first patient dosed in October 2021, the Company continues to expect that GEIS will sponsor and lead a multi-country, randomized, open-label Phase 2 clinical trial to evaluate camsirubicin head-to-head against doxorubicin, the current first-line treatment for ASTS. The Company will provide study drug and supplemental financial support for the clinical trial. During the three months ended March 31, 2021, the Company incurred \$0.3 million in expenses under the GEIS agreement and other clinical-related expenses including clinical material manufacturing and database management expenses in support of the then-planned GEIS Phase 2 camsirubicin clinical trial. The Company can terminate the agreement by providing GEIS with advance notice, and without affecting the Company's rights and ownership to any related intellectual property or clinical data. In the second quarter of 2021, due to regulatory delays in Spain, Monopar decided to conduct an open-label Phase 1b clinical trial of camsirubicin in the U.S., therefore no expenses were incurred related to the GEIS collaboration beyond March 31, 2021.

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XOMA Ltd.

The intellectual property rights contributed by Tactic Pharma to the Company included the non-exclusive license agreement with XOMA Ltd. for the humanization technology used in the development of MNPR-101. Pursuant to such license agreement, the Company is obligated to pay XOMA Ltd. clinical, regulatory and sales milestones for MNPR-101 that could reach up to \$14.925 million if the Company achieves all milestones. The agreement does not require the payment of sales royalties. There can be no assurance that the Company will reach any milestones under the XOMA agreement. As of March 31, 2022, the Company had not reached any milestones and has not been required to pay XOMA Ltd. any funds under this license agreement.

Leases

The Company is currently leasing office space for its executive headquarters at 1000 Skokie Blvd., in the Village of Wilmette, Illinois for \$4,238 per month. In February 2022, the Company entered into a two-year lease for 1,202 square feet of the office space for \$2,379 per month. The additional office space, leased for \$1,859 per month is on a month-to-month basis.

As of March 31, 2022, in accordance with ASC 842, *Leases*, the two-year lease was recorded as a right-of-use asset (“ROU”) included in other non-current assets and a lease liability included in accounts payable, accrued expenses and other current liabilities, and other non-current liabilities on the Company’s condensed consolidated balance sheet. The adoption of ASC 842, *Leases*, had no impact on previously reported stockholders’ equity. The ROU asset and associated liability is equal to the present value of the minimum lease payments. Since the rate implicit in the lease is rarely readily determinable the Company applied an incremental borrowing rate taking into consideration with our credit quality and borrowing rate for similar assets. The lease terms used to calculate the ROU asset and related lease liability does not include an option to extend but does include an option to terminate the lease. Lease costs for operating leases are recognized on a straight-line basis over the expected lease term and recorded as general and administrative expenses on the Company’s statements of operations and comprehensive loss. Amortization of the ROU asset will commence on April 1, 2022.

The components of lease expense were as follows:

	Three Months Ended March	
	31,	
	2022	2021
Total month-to-month lease costs	\$ 11,083	\$ 13,462

Maturities of the lease liability as of March 31, 2022 are as follows:

Year Ending	Operating Leases
December 31, 2022	\$ 21,411
December 31, 2023	28,548
December 31, 2024	4,758
Total lease payments	54,717
Less: imputed interest	(3,402)
Total lease liability as of March 31, 2022	\$ 51,315

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The following table presents the weighted average remaining lease term and the discount rate used in calculating the ROU asset and related lease liability for the periods presented:

	March 31,	
	2022	2021
Lease term:		
Operating lease	1.92 years	—
Discount rate:		
Operating lease	6.50%	—

Supplemental balance sheet information:

	March 31,	
	2022	2021
Total ROU non-current asset	\$ 53,694	—
Operating lease liability - current	\$ 25,977	—
Operating lease liability - non-current	25,338	—
Total operating lease liability	\$ 51,315	—

Legal Contingencies

The Company may be subject to claims and assessments from time to time in the ordinary course of business. No claims have been asserted to date.

Indemnification

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and provide for general indemnification. The Company's exposure under these agreements is unknown because it involves claims that may be made against the Company in the future, but that have not yet been made. To date, the Company has not paid any claims nor been required to defend any action related to its indemnification obligations. However, the Company may record charges in the future as a result of future claims against these indemnification obligations.

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In accordance with its second amended and restated certificate of incorporation, amended and restated bylaws and the indemnification agreements entered into with each officer and non-employee director, the Company has indemnification obligations to its officers and non-employee directors for certain events or occurrences, subject to certain limits, while they are serving at the Company's request in such capacities. There have been no indemnification claims to date.

Note 7 – Subsequent Events

On April 20, 2022, the Company executed a Capital on DemandTM Sales Agreement with JonesTrading Institutional Services LLC, pursuant to which Monopar may offer and sell, from time to time, through or to JonesTrading, as sales agent or principal, shares of Monopar's common stock. On April 20, 2022, the Company filed a prospectus supplement with the U.S. Securities and Exchange Commission relating to the offer and sale of its common stock from time to time pursuant to the agreement up to an aggregate amount of \$4,870,000.

Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations.

You should read the following discussion and analysis of our financial condition and results of operations together with our condensed consolidated financial statements and related notes contained in this Quarterly Report on Form 10-Q. Some of the information contained in this discussion and analysis are set forth elsewhere in this Quarterly Report on Form 10-Q, including information with respect to our plans and strategy for our business and related financing activities, includes forward-looking statements that involve risks and uncertainties.

Overview

We are a clinical stage biopharmaceutical company focused on developing proprietary therapeutics designed to extend life or improve quality of life for cancer patients. We are building a drug development pipeline through the licensing and acquisition of therapeutics in late preclinical and clinical development stages. We leverage our scientific and clinical experience to help reduce the risk of and accelerate the clinical development of our drug product candidates.

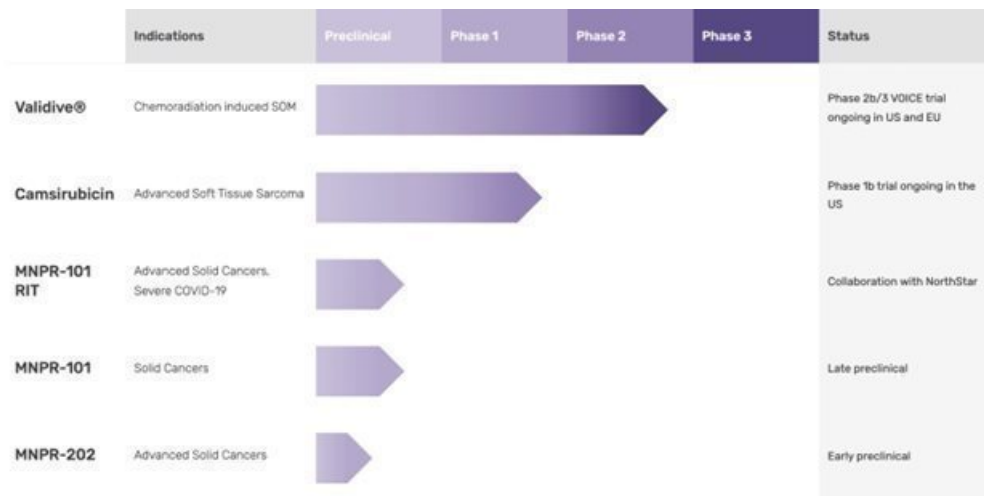
Financial Status

The balance of cash and cash equivalents as of March 31, 2022, was \$17.8 million. As discussed further below and elsewhere in this report, we expect that our current funds will be sufficient for us to obtain topline results from our ongoing open-label Phase 1b camsirubicin clinical trial as planned by June 2023 (but, as discussed below, this may not be the case if camsirubicin reaches even higher dose levels than we are anticipating and topline results are deferred as dosing continues beyond June 2023) and to complete the Phase 2b and commence the Phase 3 portion of our ongoing Validive VOICE clinical program. We will require additional funding to advance our clinical programs and we anticipate that we will seek to raise additional capital within the next 12 months to fund our future operations.

Our primary funding source in 2020 and 2021 was sales of shares of our common stock under an at-the-market sales program. During 2020 and the first quarter of 2021, we sold 1,964,724 shares of our common stock at an average gross price of \$10.02 per share for net proceeds of \$19,100,603, after fees and commissions of \$591,188. The maximum aggregate offering price under the agreement was reached during the first quarter of 2021 and there will not be further sales under this agreement.

However, on April 20, 2022, we entered into a new Capital on DemandTM Sales Agreement (the “Agreement”) with JonesTrading Institutional Services LLC (“JonesTrading” or the “Agent”), pursuant to which we may offer and sell, from time to time, through or to JonesTrading, as sales agent or principal, shares of our common stock. Also on April 20, 2022, the we filed a prospectus supplement with the U.S. Securities and Exchange Commission (the “SEC”) relating to the offer and sale of our common stock from time to time pursuant to the Agreement up to an aggregate amount of \$4,870,000. To date, we have not sold any shares under this Agreement.

Our Product Pipeline



Validive® (clonidine hydrochloride mucobuccal tablet; clonidine HCl MBT) Clinical Update

In February 2021, we dosed the first patient in our Phase 2b/3 VOICE trial of Validive for the prevention of chemoradiation treatment (“CRT”)-induced **severe oral mucositis** in patients with oropharyngeal cancer (“VOICE”). In August 2021, we successfully reached our original target of 20 activated clinical trial sites for the Phase 2b portion of the 2b/3 Validive® VOICE trial and in September 2021, we received authorization to proceed with the VOICE clinical trial in multiple countries in Europe. In February 2022, we announced that 44 clinical sites have been opened to date and are active and enrolling patients in both the U.S. and Europe, and that based on findings extracted from public reporting of recently completed SOM trials, we are presently evaluating potential enhancements to and exact timing of the interim analysis. The interim analysis is currently anticipated to be reached in the second half of 2022. We plan to continue to activate additional sites globally. To complete the VOICE clinical program, including, if required, completing a second Phase 3 confirmatory clinical trial, we will require additional funding in the millions or tens of millions of dollars (depending on if we have consummated a collaboration or partnership or neither for Validive), which we are planning to pursue within the next 12 months.

Camsirubicin Clinical Update

In August 2021, we announced clearance from the U.S. Food and Drug Administration (“FDA”) to proceed with an open-label Phase 1b dose-escalation clinical trial evaluating camsirubicin plus growth factor support (pegfilgrastim/G-CSF) in patients with advanced soft tissue sarcoma (“ASTS”). In September 2021, we initiated the Phase 1b clinical trial, and in October 2021, we dosed the first patients. In February 2022, we announced that the first dose level of camsirubicin had been completed in November 2021, with a positive recommendation from the trial safety review committee to proceed to next higher dose level and that three patients had already been dosed at the second dose level, with early signs of clinical benefit observed across the first two dose levels. That dose level was successfully cleared, as was the third dose level, and we are now currently enrolling patients in the fourth dose-level. The fourth dose-level is almost twice the highest dose reached in any prior camsirubicin clinical trial (520mg/m² versus 265 mg/m²). The open-label Phase 1b camsirubicin dose-escalation trial is continuing to enroll additional cohorts until the maximum tolerable dose is reached. Following completion of the Phase 1b clinical trial, we continue to expect that Grupo Español de Investigación en Sarcomas (“GEIS”), with whom we have a collaboration agreement, will sponsor and lead a multi-country, randomized, open-label Phase 2 clinical trial to evaluate camsirubicin head-to-head against doxorubicin, the current first-line treatment for ASTS. We currently anticipate topline results in the camsirubicin Phase 1b clinical trial by June 2023 and believe we have sufficient funds to advance the trial through that date. However, if camsirubicin reaches even higher dose levels than we are anticipating, the Phase 1b clinical trial may still be dosing patients beyond June 2023 and topline results may be deferred. Although we would likely consider this a positive development, it is possible that we would require additional funding to complete an extended Phase 1b clinical trial in this situation. Regardless, additional funding is expected to be required to support further development beyond the Phase 1b clinical trial.

MNPR-101 RIT Development Update

Pursuant to our 50/50 collaboration development agreement with NorthStar Medical Radioisotopes, LLC (“NorthStar”) to develop potential radioimmunotherapeutics (“RITs”) to treat severe COVID-19 (patients with SARS-CoV-2 infection) and advanced cancer, we have coupled MNPR-101 to therapeutic radioisotopes supplied by NorthStar. The resulting conjugates are designed to be highly selective agents that have the potential to kill aberrantly activated cytokine-producing immune cells. By eradicating these cells with a uPAR-targeted RIT (“uPRIT”), the therapeutic goal is to spare healthy cells while quickly reducing the cytokine storm and its harmful systemic effects. In addition, Monopar and NorthStar have advanced their collaboration to investigate MNPR-101 coupled to diagnostic radioisotopes as a companion diagnostic for uPRIT for use in advanced cancers and severe COVID-19.

In February 2022, we announced that our NorthStar collaboration generated a radioimmunotherapeutic candidate, MNPR-101-PCTA, that is being evaluated as a potential diagnostic and therapeutic agent (same backbone but utilizing a different radioisotope as the diagnostic) in advanced cancer and severe COVID-19, and that we are currently evaluating pathways to initiating a first-in-human study.

MNPR-202 and Related Analogs Updates

In June 2021, we entered into a collaboration agreement with the Cancer Science Institute of Singapore (“CSI Singapore”), one of Asia’s premier cancer research centers, at the National University of Singapore (“NUS”) (consistently ranked as one of the world’s top universities) to evaluate the activity of MNPR-202 and related analogs in multiple types of cancer. MNPR-202 was designed to retain the same potentially non-cardiotoxic backbone as camsirubicin but is modified at other positions which may enable it to work in certain cancers that are resistant to camsirubicin and doxorubicin. In December 2020, we announced the issuance of our composition of matter U.S. patent (US10,450,340) covering MNPR-202 and related analogs. CSI Singapore is testing MNPR-202 in preclinical cancer models and we are awaiting their results.

Our Strategy

Our management team has extensive experience in developing therapeutics and medical technologies through global regulatory approval and commercialization. In aggregate, companies they co-founded have achieved four drug approvals and three diagnostic medical imaging device approvals in the U.S. and the EU, successfully sold an asset developed by management which is currently in Phase 3 clinical trials, sold two oncology-focused diagnostic imaging businesses to Fortune Global 1000 firms, and completed the clinical and commercial development and ultimately the sale of a commercial biopharmaceutical company for over \$800 million in cash. In addition, the team has supported multiple regulatory submissions with the FDA and EMA and launched multiple drugs in the U.S and the EU. Understanding the preclinical, clinical, regulatory and commercial development processes and hurdles are key factors in successful drug development and the expertise demonstrated by our management team across all of these areas increases the probability of success in advancing the product candidates in our product pipeline. Our strategic goal is to acquire, develop and commercialize promising oncology product candidates that address important unmet medical needs of cancer patients. Seven key elements of our strategy to achieve this goal are to:

- **Leverage data generated from the Phase 2 Validive clinical trial to complete the execution of a successful VOICE clinical program for Validive for SOM in oropharyngeal cancer (“OPC”).** In the prior Phase 2 clinical trial the absolute incidence of SOM in OPC patients was reduced by 26.3%, the time to SOM onset was delayed, and the duration of disease in patients that developed SOM was decreased by 15.5 days in the Validive 100 µg cohort versus placebo. In addition to the data from the Phase 2 clinical trial, we believe the guidance from our key opinion leaders (“KOLs”) as well as from the FDA and EMA, and our own internal clinical trial design expertise, position us well for an effective VOICE clinical trial program.
- **Obtain FDA and EMA approval of Validive to maximize the commercial potential of Validive in both the U.S. and the EU, and seek partnerships outside these markets.** If the VOICE clinical program of Validive is successful and FDA and EMA approvals are obtained, we currently intend to commercialize Validive in the U.S. and the EU ourselves, which may include establishing our own specialty sales force and seeking partnerships outside of these territories for regulatory approval and drug sales and distribution.

- **Advance the clinical development of camsirubicin, by pursuing indications where doxorubicin has demonstrated efficacy.** ASTS will be the first indication, which is anticipated to allow camsirubicin to go head-to-head against doxorubicin, the current first-line treatment. In this indication, camsirubicin previously demonstrated clinical benefit (stable disease or partial response) in 52.6% of patients evaluable for tumor progression in a single-arm Phase 2 study. Clinical benefit was proportional to dose and was consistently observed at higher cumulative doses of camsirubicin (>1000 mg/m²). Camsirubicin was very well tolerated in this Phase 2 study and underscored the ability to potentially administer camsirubicin without restriction as to cumulative dose (doxorubicin is limited due to heart toxicity to 450 mg/m² cumulative dose). Our current ongoing Phase 1b clinical trial continues towards establishing a new, higher recommended dose for the next Phase 2 ASTS clinical trial.
- **Continue the development of MNPR-101, MNPR-101 RIT and related molecules as therapeutic, diagnostic and imaging agents.** We plan to continue the development of MNPR-101, MNPR-101 RIT and related molecules for diagnostic, imaging, and therapeutic use in cancer and severe COVID-19.
- **Continue the development of MNPR-202 and related analogs in multiple types of cancers.** The 2-pyrillino camsirubicin analog (MNPR-202) and related analogs represent proprietary compositions of matter designed to retain the non-cardiotoxic backbone of camsirubicin yet exhibit novel features in terms of antitumor activity and mechanism that distinguish these analogs from camsirubicin as well as from doxorubicin.
- **Expand our drug development pipeline through advancing current assets, in-licensing, and acquisition of oncology product candidates.** We plan to continue the expansion of our drug development pipeline through acquiring or in-licensing additional oncology product candidates, particularly those that leverage existing scientific and clinical data that helps reduce the risks of the next steps in clinical development.
- **Utilize the expertise and prior experience of our team in the areas of asset acquisition, drug development and commercialization to establish ourselves as a leading biopharmaceutical company.** Our senior executive team has relevant experience in biopharmaceutical in-licensing and acquisitions as well as developing product candidates through approval and commercialization. In aggregate, our team has co-founded BioMarin Pharmaceutical (Nasdaq: BMRN), Sensant Corp (acquired by Siemens), American BioOptics (assets acquired by Olympus), Raptor Pharmaceuticals (\$800 million sale to Horizon Pharma), and Tactic Pharma, LLC (“Tactic Pharma”) (sale of lead asset, choline tetrathiomolybdate, was ultimately acquired by Alexion in June 2018 for \$764 million; Alexion was subsequently acquired by AstraZeneca).

Revenues

We are an emerging growth company. We have no approved drugs and have not generated any revenue. To date, we have engaged in acquiring or in-licensing pharmaceutical drug product candidates, entering into collaboration agreements for testing and clinical development of our drug product candidates and providing the infrastructure to support the clinical development of our drug product candidates. We do not anticipate commercial revenues from operations until we complete testing and development of one of our drug product candidates and obtain marketing approval or we sell, enter into a collaborative marketing arrangement, or out-license one of our drug product candidates to another party. See “Liquidity and Capital Resources”.

Recently Issued and Adopted Accounting Pronouncements

During the three months ended March 31, 2022, there were no relevant recently issued accounting pronouncements that would impact our financial position and our condensed consolidated statements of operations and comprehensive loss.

Critical Accounting Policies and Use of Estimates

While our significant accounting policies are described in more detail in Note 2 of our condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q, we believe the following accounting policies to be critical to the judgments and estimates used in the preparation of our condensed consolidated financial statements.

Clinical Trials Accruals

We accrue and expense the costs for clinical trial activities performed by third parties based upon estimates of the percentage of work completed over the life of the individual study in accordance with agreements established with contract research organizations, service providers, and clinical trial sites. We estimate the amounts to accrue based upon discussions with internal clinical personnel and external service providers as to progress or stage of completion of trials or services and the agreed upon fee to be paid for such services. Costs of setting up clinical trial sites for participation in the trials are expensed immediately as R&D expenses. Clinical trial site costs related to patient screening and enrollment are accrued as patients are screened/entered into the trial.

Stock-Based Compensation

We account for stock-based compensation arrangements with employees, non-employee directors and consultants using a fair value method, which requires the recognition of compensation expense for costs related to all stock-based awards, including stock option grants and restricted stock units (“RSUs”). The fair value method requires us to estimate the fair value of stock-based payment awards on the date of grant using an option pricing model or the closing stock price on the date of grant in the case of RSUs.

Stock-based compensation costs for stock awards granted to our employees, non-employee directors and consultants are based on the fair value of the underlying instruments calculated using the Black-Scholes option-pricing model on the date of grant for stock options and using the closing stock price on the date of grant for RSUs and recognized as expense on a straight-line basis over the requisite service period, which is the vesting period. Determining the appropriate fair value model and related assumptions requires judgment, including selecting methods for estimating our future stock price volatility and expected term. The expected volatility rates are estimated based on our actual historical volatility over the two-year period from our initial public offering on December 18, 2019, through December 31, 2021. The expected term for stock options granted during the three months ended March 31, 2022, and 2021, was estimated using the simplified method. Forfeitures only include known forfeitures to-date as the Company accounts for forfeitures as they occur due to a limited history of forfeitures. We have not paid dividends and do not anticipate paying a cash dividend in future vesting periods and, accordingly, use an expected dividend yield of zero. The risk-free interest rate is based on the rate of U.S. Treasury securities with maturities consistent with the estimated expected term of the awards.

Results of Operations**Comparison of the Three Months Ended March 31, 2022, and 2021**

The following table summarizes the results of our operations for the three months ended March 31, 2022, and 2021:

(in thousands)	Three Months Ended March 31, (Unaudited)		
	2022	2021	Variance
Research and development expenses	\$ 1,678	\$ 1,207	\$ 471
General and administrative expenses	779	688	91
Total operating expenses	2,457	1,895	562
Operating loss	(2,457)	(1,895)	(562)
Interest income	—	11	(11)
Net loss	\$ (2,457)	\$ (1,884)	\$ (573)

Research and Development (“R&D”) Expenses

R&D expenses for the three months ended March 31, 2022 were \$1,678,000, compared to \$1,207,000 for the three months ended March 31, 2021. This represents an increase of \$471,000 attributed to (1) an increase of \$244,000 in Validive clinical trial-related and clinical material manufacturing-related expenses, (2) an increase of \$193,000 in personnel costs resulting from an increase in (non-cash) stock-based compensation expense for R&D personnel combined with the partial allocation of the increased CEO's salary and benefits to R&D expenses and (3) a \$34,000 net increase of other R&D expenses.

General and Administrative Expenses

General and administrative (“G&A”) expenses for the three months ended March 31, 2022 were \$779,000, compared to \$688,000 for the three months ended March 31, 2021. This represents an increase of \$91,000 primarily attributed to an increase in G&A salaries and benefits.

Interest Income

Interest income for the three months ended March 31, 2022, decreased by \$11,000 versus the three months ended March 31, 2021, due to a significant decrease in bank interest rates and reduced levels of cash.

Liquidity and Capital Resources**Sources of Liquidity**

We have incurred losses and cumulative negative cash flows from operations since our inception in December 2015 resulting in an accumulated deficit of approximately \$43.7 million as of March 31, 2022. We anticipate that we will continue to incur losses for the foreseeable future. We expect that our R&D and G&A expenses will increase to enable the execution of our strategic plan. As a result, we anticipate that we will seek to raise additional capital within the next 12 months to fund our future operations. We will seek to obtain needed capital through a combination of equity offerings, including the usage of our Capital on Demand™ Sales Agreement with JonesTrading, debt financings, strategic collaborations and grant funding. To date, we have funded our operations through net proceeds from the initial public offering of our common stock and net proceeds from sales of our common stock through an at-the-market sales program, private placements of our preferred and common stock, and the net receipt of funds related to the acquisition of camsirubicin. We anticipate that the currently available funds as of April 30, 2022, will fund our planned operations at least through June 30, 2023.

We invest our cash in a money market account.

Cash Flows

The following table provides information regarding our cash flows for the three months ended March 31, 2022, and 2021.

(in thousands)	Three Months Ended March 31, (Unaudited)		
	2022	2021	Variance
Net cash used in operating activities	\$ (2,467)	\$ (1,938)	\$ (529)
Net cash provided by (used in) financing activities	(17)	10,921	(10,938)
Effect of exchange rates	(1)	3	(4)
Net increase (decrease) in cash and cash equivalents	<u>\$ (2,485)</u>	<u>\$ 8,986</u>	<u>\$ (11,471)</u>

Cash Flow Used in Operating Activities

The increase of \$529,000 in cash flow used in operating activities during the three months ended March 31, 2022, compared to the three months ended March 31, 2021, was primarily a result of increases in salaries and benefits expenses and R&D cash operating expenses.

Cash Flow Used in Investing Activities

There was no cash flow used in investing activities for the three months ended March 31, 2022, and 2021.

Cash Flow Provided by (Used in) Financing Activities

The decrease in cash flow provided by financing activities during the three months ended March 31, 2022, compared to the three months ended March 31, 2021, of \$10,938,000 was primarily due to the proceeds from sales of our common stock under an at-the-market sales program during the three months ended March 31, 2021.

Future Funding Requirements

To date, we have not generated any revenue from product sales. We do not know when, or if, we will generate any revenue from product sales. We do not expect to generate any revenue from product sales or royalties unless and until we obtain regulatory approval of and commercialize any of our current or future drug product candidates or we out-license or sell a drug product candidate to another party. At the same time, we expect our expenses to increase in connection with our ongoing development activities, particularly as we continue the research, development, future preclinical studies and clinical trials of, and seek regulatory approval for, our current and future drug product candidates. If we obtain regulatory approval of any of our current or future drug product candidates, we will need substantial additional funding for commercialization requirements and our continuing drug product development operations.

As a company, we have not completed development through marketing approvals of any therapeutic products. We expect to continue to incur significant increases in expenses and increasing operating losses for the foreseeable future. We anticipate that our expenses will increase substantially as we:

- advance the clinical development and execute the regulatory strategy for Validive;
- advance the clinical development and execute the regulatory strategy for camsirubicin;
- continue the preclinical activities and potentially enter clinical development of MNPR-101 and MNPR-101-derived radioimmunotherapeutics and companion diagnostics, to treat cancer and severe COVID-19 (patients with SARS-CoV-2 infection);
- continue the preclinical activities, and potentially later-on enter clinical development, of MNPR-202 (and related analogs) for various cancer indications;
- acquire and/or license additional pipeline drug product candidates and pursue the future preclinical and/or clinical development of such drug product candidates;
- seek regulatory approvals for any of our current and future drug product candidates that successfully complete registration clinical trials;
- establish or purchase the services of a sales, marketing and distribution infrastructure to commercialize any products for which we obtain marketing approval;
- develop or contract for manufacturing/quality capabilities or establish a reliable, high quality supply chain sufficient to support our clinical requirements and to provide sufficient capacity to launch and supply the market for any product for which we obtain marketing approval; and
- add or contract for required operational, financial, human resources and management information systems and capabilities and other specialized expert personnel to support our drug product candidate development and planned commercialization efforts.

We anticipate that the funds available as of April 30, 2022, will fund our obligations at least through June 30, 2023. We have based this estimate on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development and commercialization of our drug product candidates, and the extent to which we enter into collaborations with third parties to participate in the development and commercialization of our drug product candidates, we are unable to accurately estimate with high reliability the amounts and timing required for increased capital outlays and operating expenditures associated with our current and anticipated drug product candidate development programs.

Our future capital requirements will depend on many factors, including:

- the progress of clinical development and regulatory interactions and potential approvals of Validive;
- the progress of clinical development and regulatory interactions and potential approvals of camsirubicin;
- the costs, timing and outcomes of seeking, obtaining, and maintaining FDA and international regulatory approvals;
- the progress of preclinical and potential clinical development of MNPR-101 and MNPR-101-derived radioimmunotherapeutics and companion diagnostics, to treat cancer and severe COVID-19 (patients with SARS-CoV-2 infection), including activities through our collaboration with NorthStar;
- the progress of preclinical and potential clinical development of MNPR-202 (and related analogs);
- the number and characteristics of other drug product candidates that we may license, acquire, invent or otherwise pursue;

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- the scope, progress, timing, cost and results of research, preclinical development and clinical trials of future drug product candidates;
- the costs associated with establishing or contracting for manufacturing/quality requirements and establishing or contracting for sales, marketing and distribution capabilities;
- our ability and related costs to maintain, expand and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make in connection with the licensing, filing, defense and enforcement of any patents or other intellectual property rights;
- our need and ability to hire or contract for additional management, administrative, scientific, medical, sales and marketing, and manufacturing/quality and other specialized personnel or external expertise;
- the effect and timing of entry of competing products or new therapies that may limit market penetration or prevent the introduction of our drug product candidates or reduce the commercial potential of our product portfolio;
- our need to implement additional required internal systems and infrastructure; and
- the economic and other terms, timing and success of our existing collaboration and licensing arrangements and any collaboration, licensing or other arrangements into which we may enter into in the future, including the timing of receipt of or payment to or from others of any milestone or royalty payments under these arrangements.

Expenditures are expected to increase in the second quarter of 2022 and onward for:

- clinical research services and clinical site fees for our VOICE clinical program, including, if required, completing a second Phase 3 confirmatory clinical trial;
- process development, manufacturing costs, clinical trial expenses and clinical database management of camsirubicin in connection with the Phase 1b dose escalation clinical trial and other future clinical development;
- support of the development of MNPR-101-derived radioimmunotherapeutics and companion diagnostics to treat cancer and severe COVID-19 (patients with SARS-CoV-2 infection), including activities through our collaboration with NorthStar;
- preclinical studies (and if successful, clinical studies) of MNPR-101, MNPR-202 (and related analogs); and
- employee compensation and consulting fees to support our product candidate programs including Validive, camsirubicin, MNPR-101, MNPR-101 RIT (uPRIT and related compounds) and companion diagnostics and MNPR-202 (and related analogs).

We have activated clinical trial sites and are dosing patients in our VOICE clinical trial. In order to complete the VOICE clinical program, including, if required, completing a second Phase 3 confirmatory clinical trial, we will require additional funding in the millions or tens of millions of dollars (depending on if we have consummated a collaboration or partnership or neither for Validive), or find a suitable pharmaceutical partner, both of which we are planning to pursue within the next 12 months. There can be no assurance that any such events will occur. We have also initiated and commenced dosing in our Phase 1b camsirubicin clinical trial. We intend to continue evaluating drug product candidates for the purpose of growing our pipeline. Identifying and securing high-quality compounds usually takes time and related expenses; however, our spending could be significantly accelerated in the second quarter of 2022 and onward if additional drug product candidates are acquired and enter clinical development. In this event, we may be required to expand our management team, and pay higher contract manufacturing costs, contract research organization fees, other clinical development costs and insurance costs that are not currently projected. Beyond our need to raise additional funding within the next 12 months to complete the VOICE clinical program, additional long-term funding is needed to commercialize Validive, if approved, and otherwise generally to support our current and future product candidates through clinical trials, approval processes and, if applicable, commercialization.

Until we can generate a sufficient amount of product revenue to finance our cash requirements, we expect to finance our future cash needs primarily through a combination of equity offerings, including the usage of our Capital on Demand™ Sales Agreement with JonesTrading, debt financings, strategic collaborations and grant funding. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our current stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our current stockholders' rights. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with other parties, we likely will have to relinquish valuable rights to our technologies, future revenue streams, research programs or drug product candidates or grant licenses on terms that may not be favorable to us, which will reduce our future returns and affect our future operating flexibility. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our pipeline product development or commercialization efforts or grant rights to others to develop and market drug product candidates that we would otherwise prefer to develop and market ourselves.

Contractual Obligations and Commitments

License, Development and Collaboration Agreements

Onxeo S.A.

In June 2016, we executed an agreement with Onxeo S.A., a French public company, which gave us the exclusive option to license (on a world-wide exclusive basis) Validive (clonidine hydrochloride mucobuccal tablet; clonidine HCl MBT) a mucoadhesive tablet of clonidine based on the Lauriad mucoadhesive technology. The agreement includes clinical, regulatory, developmental and sales milestones that could reach up to \$108 million if we achieve all milestones, and escalating royalties from 5% to 10% on net sales. In September 2017, we exercised the option to license Validive from Onxeo for \$1 million, but as of April 30, 2022, we have not been required to pay Onxeo any other funds under the agreement. We will need to raise significant funds or enter into a collaboration partnership to support the completion of clinical development and potential marketing approval of Validive.

Under the agreement, we are required to pay royalties to Onxeo on a product-by-product and country-by-country basis until the later of (1) the date when a given product is no longer within the scope of a patent claim in the country of sale or manufacture, (2) the expiry of any extended exclusivity period in the relevant country (such as orphan drug exclusivity, pediatric exclusivity, new chemical entity exclusivity, or other exclusivity granted beyond the expiry of the relevant patent), or (3) a specific time period after the first commercial sale of the product in such country. In most countries, including the U.S., the patent term is generally 20 years from the earliest claimed filing date of a non-provisional patent application in the applicable country, not taking into consideration any potential patent term adjustment that may be filed in the future or any regulatory extensions that may be obtained. The royalty termination provision pursuant to (3) described above is shorter than 20 years and is the least likely cause of termination of royalty payments.

The Onxeo license agreement does not have a pre-determined term, but expires on a product-by-product and country-by-country basis; that is, the agreement expires with respect to a given product in a given country whenever our royalty payment obligations with respect to such product have expired. The agreement may also be terminated early for cause if either we or Onxeo materially breach the agreement, or if either we or Onxeo become insolvent. We may also choose to terminate the agreement, either in its entirety or as to a certain product and a certain country, by providing Onxeo with advance notice.

Grupo Español de Investigación en Sarcomas (“GEIS”)

In June 2019, we executed a clinical collaboration with GEIS for the development of camsirubicin in patients with advanced soft tissue sarcoma (“ASTS”). Following completion of the dose escalation run-in clinical trial in the U.S. that we initiated in the third quarter of 2021 with the first patient dosed in October 2021, we continue to expect that GEIS will sponsor and lead a multi-country, randomized, open-label Phase 2 clinical trial to evaluate camsirubicin head-to-head against doxorubicin, the current first-line treatment for ASTS. We will provide study drug and supplemental financial support for the clinical trial. During the three months ended March 31, 2021, we incurred \$0.3 million in expenses under the GEIS agreement and other clinical-related expenses including clinical material manufacturing and database management expenses in support of the then-planned GEIS Phase 2 camsirubicin clinical trial. We can terminate the agreement by providing GEIS with advance notice, and without affecting our rights and ownership to any related intellectual property or clinical data. In the second quarter of 2021, due to regulatory delays in Spain, we decided to conduct an open-label Phase 1b clinical trial of camsirubicin in the U.S.; therefore, no expenses were incurred related to the GEIS collaboration beyond March 31, 2021.

XOMA Ltd.

Pursuant to a non-exclusive license agreement with XOMA Ltd. for the humanization technology used in the development of MNPR-101, we are obligated to pay XOMA Ltd. clinical, regulatory and sales milestones which could reach up to \$14.925 million if we achieve all milestones for MNPR-101. The agreement does not require the payment of sales royalties. There can be no assurance that we will achieve any milestones. As of April 30, 2022, we had not reached any milestones and had not been required to pay XOMA Ltd. any funds under this license agreement.

Service Providers

In the normal course of business, we contract with service providers to assist in the performance of R&D, including drug product manufacturing, process development, clinical and preclinical development, and G&A including financial strategy, audit, tax and legal support. We can elect to discontinue the work under these agreements at any time. We could also enter into collaborative research and development, contract research, manufacturing and supplier agreements in the future, which may require upfront payments and/or long-term commitments of cash.

Office Lease

The Company is currently leasing office space for its executive headquarters at 1000 Skokie Blvd., in the Village of Wilmette, Illinois for \$4,238 per month and we anticipate that we will lease additional space in the future as we hire additional personnel.

Legal Contingencies

We are currently not, and to date have never been, a party to any adverse material legal proceedings.

Indemnification

In the normal course of business, we enter into contracts and agreements that contain a variety of representations and warranties and provide for general indemnification. Our exposure under these agreements is unknown because it involves claims that may be made against us in the future, but that have not yet been made. To date, we have not paid any claims or been required to defend any action related to our indemnification obligations. However, we may record charges in the future as a result of these indemnification obligations.

In accordance with our Second Amended and Restated Certificate of Incorporation, Amended and Restated Bylaws and the indemnification agreements entered into with each officer and non-employee director, we have indemnification obligations to our officers and non-employee directors for certain events or occurrences, subject to certain limits, while they are serving at our request in such capacity. There have been no claims to date.

Item 4. Controls and Procedures

Our Chief Executive Officer and Chief Financial Officer have provided certifications filed as Exhibits 31.1 and 31.2, respectively, and Exhibit 32.1. Such certifications should be read in conjunction with the information contained in this Item 4 for a more complete understanding of the matters covered by those certifications.

(a) Disclosure Controls and Procedures

We carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of our disclosure controls and procedures as of March 31, 2022, pursuant to Rules 13a15(e) and 15d15(e) under the Exchange Act. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures, as of such date, were effective.

(b) Changes in Internal Control over Financial Reporting

We have concluded that the condensed consolidated financial statements and other financial information included in this Quarterly Report on Form 10-Q fairly present in all material respects our financial condition, results of operations and comprehensive loss and cash flows as of, and for, the periods presented.

There have been no changes in our internal control over financial reporting during the three months ended March 31, 2022, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1A. Risk Factors

Other than the additional risk factors below, there have been no material changes in information regarding our risk factors as described in Item 1A of our Annual Report on Form 10-K as filed with the SEC on March 24, 2022.

On April 20, 2022, we executed a Capital on DemandTM Sales Agreement with JonesTrading, pursuant to which we may offer and sell, from time to time, through or to JonesTrading, as sales agent or principal, shares of our common stock. On April 20, 2022, we filed a prospectus supplement with the SEC relating to the offer and sale of our common stock from time to time pursuant to the agreement up to an aggregate amount of \$4,870,000. This offering adds the following risk factors to our Company:

Future sales of substantial amounts of shares of our common stock, or the possibility that such sales could occur, could adversely affect the market price of our common stock.

We may issue shares of our common stock from time to time pursuant to our Capital on DemandTM Sales Agreement with JonesTrading in an aggregate price to the public of up to \$4.87 million. The issuance from time to time of the shares, as well as our ability to issue such shares, could have the effect of depressing the market price or increasing the market price volatility of our common stock.

We are likely to require substantial additional funding regardless of the number of shares of our common stock we sell under our Capital on DemandTM Sales Agreement with JonesTrading or the gross proceeds resulting from those sales.

The amount of proceeds from the Capital on DemandTM Sales Agreement with JonesTrading will depend upon the number of shares of our common stock sold and the market price at which they are sold. There can be no assurance that we will be able to sell any shares under or fully utilize the sales agreement as a source of financing. Even if we are able to sell the full \$4.87 million, we will likely require substantial additional funding and there can be no assurance such funding will be available. To date we have not sold any shares under the agreement.

Item 5. Other Information

On May 10, 2022, our Board of Directors amended and restated our bylaws. The amended and restated bylaws provide that our Board size will range from 3 to 15 members, with the number of Directors fixed at 5 as of the date of the amendment and restatement and thereafter as may be established by resolution of our Board.

Item 6. Exhibits

The following exhibits are filed as part of this Quarterly Report on Form 10-Q.

Exhibit	Document	Incorporated by Reference From:
3.1	Amended and Restated Bylaws	Filed herewith
31.1	Certification of Chandler D. Robinson, Chief Executive Officer	Filed herewith
31.2	Certification of Kim R. Tsuchimoto, Chief Financial Officer	Filed herewith
32.1	Certification of Chandler D. Robinson, Chief Executive Officer and Kim R. Tsuchimoto, Chief Financial Officer	Filed herewith
101.INS	XBRL Instance Document	
101.SCH	XBRL Taxonomy Extension Schema	
101.CAL	XBRL Taxonomy Extension Calculation Linkbase	
101.DEF	XBRL Taxonomy Extension Definition Linkbase	
101.LAB	XBRL Taxonomy Extension Label Linkbase	
101.PRE	XBRL Taxonomy Extension Presentation Linkbase	
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101)	

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.

MONOPAR THERAPEUTICS INC

Dated: May 12, 2022

By: /s/ Chandler D. Robinson
Name: Chandler D. Robinson
Title: Chief Executive Officer and Director (Principal Executive Officer)

MONOPAR THERAPEUTICS INC

Dated: May 12, 2022

By: /s/ Kim R. Tsuchimoto
Name: Kim R. Tsuchimoto
Title: Chief Financial Officer (Principal Financial Officer)

**AMENDED AND RESTATED
BY-LAWS OF
MONOPAR THERAPEUTICS INC.
(the "Corporation")**

ARTICLE I OFFICES

Section 1.01 Registered Office. The registered office of the Corporation within the State of Delaware shall be located at either (a) the principal place of business of the Corporation in the State of Delaware or (b) the office of the corporation or individual acting as the Corporation's registered agent in Delaware.

Section 1.02 Other Offices. The Corporation may also have offices at such other places, both within and outside the State of Delaware, as the acting board of directors of the Corporation (the "Board of Directors") from time to time shall determine or the business of the Corporation may require.

Section 1.03 Books and Records. Any records maintained by the Corporation in the regular course of its business, including its stock ledger, books of account and minute books, may be maintained on any information storage device or method; *provided that* the records so kept can be converted into clearly legible paper form within a reasonable time. The Corporation shall so convert any records so kept upon the request of any person entitled to inspect such records pursuant to applicable law.

**ARTICLE II
MEETINGS OF THE STOCKHOLDERS**

Section 2.01 Place of Meetings. All meetings of the stockholders shall be held at such place, if any, either within or without the State of Delaware, as shall be designated from time to time by resolution of the Board of Directors and stated in the notice of meeting. If authorized by the Board of Directors in its sole discretion, and subject to such guidelines and procedures as the Board of Directors may adopt, stockholders and proxyholders not physically present at a meeting of stockholders may, by means of remote communication participate in a meeting of stockholders; and be deemed present in person and vote at a meeting of stockholders, whether such meeting is to be held at a designated place or solely by means of remote communication, provided that (i) the Corporation shall implement reasonable measures to verify that each person deemed present and permitted to vote at the meeting by means of remote communication is a stockholder or proxyholder, (ii) the Corporation shall implement reasonable measures to provide such stockholders and proxyholders a reasonable opportunity to participate in the meeting and to vote on matters submitted to the stockholders, including an opportunity to read or hear the proceedings of the meeting substantially concurrently with such proceedings, and (iii) if any stockholder or proxyholder votes or takes other action at the meeting by means of remote communication, a record of such vote or other action shall be maintained by the Corporation.

Section 2.02 Annual Meeting. Unless directors are elected by written consent in lieu of an annual meeting as permitted by Section 2.11, the annual meeting of the stockholders for the election of directors and for the transaction of such other business as may properly come before the meeting shall be held at such date, time and place, if any, as shall be determined by the Board of Directors and stated in the notice of the meeting.

Section 2.03 Special Meetings. Special meetings of stockholders for any purpose or purposes shall be called pursuant to a resolution approved by the Board of Directors and may not be called by any other person or persons. The only business which may be conducted at a special meeting shall be the matter or matters set forth in the notice of such meeting.

Section 2.04 Adjournments. Any meeting of the stockholders, annual or special, may be adjourned from time to time to reconvene at the same or some other place, if any, and notice need not be given of any such adjourned meeting if the time, place, if any, thereof and the means of remote communication, if any, are announced at the meeting at which the adjournment is taken. At the adjourned meeting, the Corporation may transact any business which might have been transacted at the original meeting. If the adjournment is for more than 30 days, a notice of the adjourned meeting shall be given to each stockholder of record entitled to vote at the meeting. If after the adjournment a new record date is fixed for stockholders entitled to vote at the adjourned meeting, the Board of Directors shall fix a new record date for notice of the adjourned meeting and shall give notice of the adjourned meeting to each stockholder of record entitled to vote at the adjourned meeting as of the record date fixed for notice of the adjourned meeting.

Section 2.05 Notice of Meetings. Notice of the place, if any, date, hour, the record date for determining the stockholders entitled to vote at the meeting (if such date is different from the record date for stockholders entitled to notice of the meeting) and means of remote communication, if any, of every meeting of stockholders shall be given by the Corporation not less than ten days nor more than 60 days before the meeting (unless a different time is specified by law) to every stockholder entitled to vote at the meeting as of the record date for determining the stockholders entitled to notice of the meeting. Notices of special meetings shall also specify the purpose or purposes for which the meeting has been called. Except as otherwise provided herein or permitted by applicable law, notice to stockholders shall be in writing and delivered personally or mailed to the stockholders at their address appearing on the books of the Corporation. Without limiting the manner by which notice otherwise may be given effectively to stockholders, notice of meetings may be given to stockholders by means of electronic transmission in accordance with applicable law. Notice of any meeting need not be given to any stockholder who shall, either before or after the meeting, submit a waiver of notice or who shall attend such meeting, except when the stockholder attends for the express purpose of objecting, at the beginning of the meeting, to the transaction of any business because the meeting is not lawfully called or convened. Any stockholder so waiving notice of the meeting shall be bound by the proceedings of the meeting in all respects as if due notice thereof had been given.

Section 2.06 List of Stockholders. The officer of the Corporation who has charge of the stock ledger shall prepare a complete list of the stockholders entitled to vote at any meeting of stockholders (provided, however, if the record date for determining the stockholders entitled to vote is less than ten days before the date of the meeting, the list shall reflect the stockholders entitled to vote as of the tenth day before the meeting date), arranged in alphabetical order, and showing the address of each stockholder and the number of shares of each class of capital stock of the Corporation registered in the name of each stockholder at least ten days before any meeting of the stockholders. Such list shall be open to the examination of any stockholder, for any purpose germane to the meeting, on a reasonably accessible electronic network if the information required to gain access to such list was provided with the notice of the meeting or during ordinary business hours, at the principal place of business of the Corporation for a period of at least ten days before the meeting. If the meeting is to be held at a place, the list shall also be produced and kept at the time and place of the meeting the whole time thereof and may be inspected by any stockholder who is present. If the meeting is held solely by means of remote communication, the list shall also be open for inspection by any stockholder during the whole time of the meeting as provided by applicable law. Except as provided by applicable law, the stock ledger of the Corporation shall be the only evidence as to who are the stockholders entitled to examine the stock ledger and the list of stockholders or to vote in person or by proxy at any meeting of stockholders.

Section 2.07 Quorum. Unless otherwise required by law, the Corporation's Certificate of Incorporation (the "**Certificate of Incorporation**") or these by-laws, at each meeting of the stockholders, a majority in voting power of the shares of the Corporation entitled to vote at the meeting, present in person or represented by proxy, shall constitute a quorum. If, however, such quorum shall not be present or represented at any meeting of the stockholders, the stockholders entitled to vote thereat, present in person or represented by proxy, shall have power, by the affirmative vote of a majority in voting power thereof, to adjourn the meeting from time to time, in the manner provided in Section 2.04, until a quorum shall be present or represented. A quorum, once established, shall not be broken by the subsequent withdrawal of enough votes to leave less than a quorum. At any such adjourned meeting at which there is a quorum, any business may be transacted that might have been transacted at the meeting originally called.

Section 2.08 Conduct of Meetings. The Board of Directors may adopt by resolution such rules and regulations for the conduct of the meeting of the stockholders as it shall deem appropriate. At every meeting of the stockholders, the President, or in his or her absence or inability to act, the Vice President, or, in his or her absence or inability to act, the person whom the President shall appoint, shall act as chairman of, and preside at, the meeting. The secretary or, in his or her absence or inability to act, the person whom the chairman of the meeting shall appoint secretary of the meeting, shall act as secretary of the meeting and keep the minutes thereof. Except to the extent inconsistent with such rules and regulations as adopted by the Board of Directors, the chairman of any meeting of the stockholders shall have the right and authority to prescribe such rules, regulations and procedures and to do all such acts as, in the judgment of such chairman, are appropriate for the proper conduct of the meeting. Such rules, regulations or procedures, whether adopted by the Board of Directors or prescribed by the chairman of the meeting, may include, without limitation, the following: (a) the establishment of an agenda or order of business for the meeting; (b) the determination of when the polls shall open and close for any given matter to be voted on at the meeting; (c) rules and procedures for maintaining order at the meeting and the safety of those present; (d) limitations on attendance at or participation in the meeting to stockholders of record of the corporation, their duly authorized and constituted proxies or such other persons as the chairman of the meeting shall determine; (e) restrictions on entry to the meeting after the time fixed for the commencement thereof; and (f) limitations on the time allotted to questions or comments by participants.

Section 2.09 Voting; Proxies. Unless otherwise required by law or the Certificate of Incorporation the election of directors shall be decided by a plurality of the votes cast at a meeting of the stockholders by the holders of stock entitled to vote in the election. Unless otherwise required by law, the Certificate of Incorporation or these by-laws, any matter, other than the election of directors, brought before any meeting of stockholders shall be decided by the affirmative vote of the majority of shares present in person or represented by proxy at the meeting and entitled to vote on the matter. Each stockholder entitled to vote at a meeting of stockholders or to express consent to corporate action in writing without a meeting may authorize another person or persons to act for such stockholder by proxy, but no such proxy shall be voted or acted upon after three years from its date, unless the proxy provides for a longer period. A proxy shall be irrevocable if it states that it is irrevocable and if, and only as long as, it is coupled with an interest sufficient in law to support an irrevocable power. A stockholder may revoke any proxy which is not irrevocable by attending the meeting and voting in person or by delivering to the secretary of the Corporation a revocation of the proxy or a new proxy bearing a later date. Voting at meetings of stockholders need not be by written ballot.

Section 2.10 Inspectors at Meetings of Stockholders. The Board of Directors, in advance of any meeting of stockholders, may, and shall if required by law, appoint one or more inspectors, who may be employees of the Corporation, to act at the meeting or any adjournment thereof and make a written report thereof. The Board of Directors may designate one or more persons as alternate inspectors to replace any inspector who fails to act. If no inspector or alternate is able to act at a meeting, the person presiding at the meeting shall appoint one or more inspectors to act at the meeting. Each inspector, before entering upon the discharge of his or her duties, shall take and sign an oath faithfully to execute the duties of inspector with strict impartiality and according to the best of his or her ability. The inspectors shall (a) ascertain the number of shares outstanding and the voting power of each, (b) determine the shares represented at the meeting, the existence of a quorum and the validity of proxies and ballots, (c) count all votes and ballots, (d) determine and retain for a reasonable period a record of the disposition of any challenges made to any determination by the inspectors and (e) certify their determination of the number of shares represented at the meeting and their count of all votes and ballots. The inspectors may appoint or retain other persons or entities to assist the inspectors in the performance of their duties. Unless otherwise provided by the Board of Directors, the date and time of the opening and the closing of the polls for each matter upon which the stockholders will vote at a meeting shall be announced at the meeting. No ballot, proxies, votes or any revocation thereof or change thereto, shall be accepted by the inspectors after the closing of the polls unless the Court of Chancery of the State of Delaware upon application by a stockholder shall determine otherwise. In determining the validity and counting of proxies and ballots cast at any meeting of stockholders, the inspectors may consider such information as is permitted by applicable law. No person who is a candidate for office at an election may serve as an inspector at such election.

Section 2.11 Written Consent of Stockholders Without a Meeting. Any action to be taken at any annual or special meeting of stockholders may be taken without a meeting, without prior notice and without a vote, if a consent or consents in writing, setting forth the action to be so taken, shall be signed by the holders of outstanding stock having not less than the minimum number of votes that would be necessary to authorize or take such action at a meeting at which all shares entitled to vote thereon were present and voted and shall be delivered (by hand or by certified or registered mail, return receipt requested) to the Corporation by delivery to its registered office in the State of Delaware, its principal place of business or an officer or agent of the Corporation having custody of the book in which proceedings of meetings of stockholders are recorded. Every written consent shall bear the date of signature of each stockholder who signs the consent, and no written consent shall be effective to take the corporate action referred to therein unless, within 60 days of the earliest dated consent delivered in the manner required by this Section, written consents signed by a sufficient number of holders to take action are delivered to the Corporation as aforesaid. Prompt notice of the taking of the corporate action without a meeting by less than unanimous written consent shall, to the extent required by applicable law, be given to those stockholders who have not consented in writing, and who, if the action had been taken at a meeting, would have been entitled to notice of the meeting if the record date for notice of such meeting had been the date that written consents signed by a sufficient number of holders to take the action were delivered to the Corporation. Stockholders may act by written consent to elect directors; provided, however, that, if such consent is less than unanimous, such action by written consent may be in lieu of holding an annual meeting only if all of the directorships to which directors could be elected at an annual meeting held at the effective time of such action are vacant and are filled by such action.

Section 2.12 Fixing the Record Date.

(a) In order that the Corporation may determine the stockholders entitled to notice of or to vote at any meeting of stockholders or any adjournment thereof, the Board of Directors may fix a record date, which record date shall not precede the date upon which the resolution fixing the record date is adopted by the Board of Directors, and which record date shall not be more than 60 nor less than ten days before the date of such meeting. If the Board of Directors so fixes a date, such date shall also be the record date for determining the stockholders entitled to vote at such meeting unless the Board of Directors determines, at the time it fixes such record date, that a later date on or before the date of the meeting shall be the date for making such determination. If no record date is fixed by the Board of Directors, the record date for determining stockholders entitled to notice of or to vote at a meeting of stockholders shall be at the close of business on the day next preceding the day on which notice is given, or, if notice is waived, at the close of business on the day next preceding the day on which the meeting is held. A determination of stockholders of record entitled to notice of or to vote at a meeting of stockholders shall apply to any adjournment of the meeting; *provided, however*, that the Board of Directors may fix a new record date for the determination of stockholders entitled to vote at the adjourned meeting and in such case shall also fix as the record date for stockholders entitled to notice of such adjourned meeting the same or an earlier date as that fixed for the determination of stockholders entitled to vote therewith at the adjourned meeting.

(b) In order that the Corporation may determine the stockholders entitled to consent to corporate action in writing without a meeting, the Board of Directors may fix a record date, which record date shall not precede the date upon which the resolution fixing the record date is adopted by the Board of Directors, and which record date shall not be more than ten days after the date upon which the resolution fixing the record date is adopted by the Board of Directors. If no record date has been fixed by the Board of Directors, the record date for determining stockholders entitled to consent to corporate action in writing without a meeting: (i) when no prior action by the Board of Directors is required by law, the record date for such purpose shall be the first date on which a signed written consent setting forth the action taken or proposed to be taken is delivered to the Corporation by delivery (by hand, or by certified or registered mail, return receipt requested) to its registered office in the State of Delaware, its principal place of business, or an officer or agent of the Corporation having custody of the book in which proceedings of meetings of stockholders are recorded and (ii) if prior action by the Board of Directors is required by law, the record date for such purpose shall be at the close of business on the day on which the Board of Directors adopts the resolution taking such prior action.

(c) In order that the Corporation may determine the stockholders entitled to receive payment of any dividend or other distribution or allotment of any rights or the stockholders entitled to exercise any rights in respect of any change, conversion or exchange of stock, or for the purpose of any other lawful action, the Board of Directors may fix a record date, which record date shall not precede the date upon which the resolution fixing the record date is adopted, and which record date shall be not more than 60 days prior to such action. If no record date is fixed, the record date for determining stockholders for any such purpose shall be at the close of business on the day on which the Board of Directors adopts the resolution relating thereto.

ARTICLE III BOARD OF DIRECTORS

Section 3.01 General Powers. The business and affairs of the Corporation shall be managed by or under the direction of the Board of Directors. The Board of Directors may adopt such rules and procedures, not inconsistent with the Certificate of Incorporation, these by-laws or applicable law, as it may deem proper for the conduct of its meetings and the management of the Corporation.

Section 3.02 Number; Term of Office. The number of directors of the Corporation shall not be less than three nor more than fifteen. The number of directors shall, at the date of adoption of these amended and restated Bylaws, be fixed at five, and hereafter, such number of directors may be fixed from time to time exclusively by resolution of the Board of Directors. Each director shall hold office for a period of one year and until a successor is duly elected and qualified or until the director's earlier death, resignation, disqualification or removal.

Section 3.03 Newly Created Directorships and Vacancies. Any newly created directorships resulting from an increase in the authorized number of directors and any vacancies occurring in the Board of Directors, may be filled exclusively by the affirmative votes of a majority of the remaining members of the Board of Directors, although less than a quorum, or by a sole remaining director. A director so elected shall be elected to hold office until the earlier of the expiration of the term of office of the director whom he or she has replaced, a successor is duly elected and qualified or the earlier of such director's death, resignation or removal.

Section 3.04 Resignation. Any director may resign at any time by notice given in writing or by electronic transmission to the Corporation. Such resignation shall take effect at the date of receipt of such notice by the Corporation or at such later time as is therein specified.

Section 3.05 Removal. Except as prohibited by applicable law or the Certificate of Incorporation, the stockholders entitled to vote in an election of directors may remove any director from office at any time, with or without cause, by the affirmative vote of a majority in voting power thereof.

Section 3.06 Fees and Expenses. Directors shall receive such fees, which may include equity compensation, and expenses as the Board of Directors shall from time to time prescribe.

Section 3.07 Regular Meetings. Regular meetings of the Board of Directors may be held without notice at such times and at such places as may be determined from time to time by the Board of Directors or its chairman.

Section 3.08 Special Meetings. Special meetings of the Board of Directors may be held at such times and at such places as may be determined by the chairman or the President on at least 24 hours' notice to each director given by one of the means specified in **Section 3.11** hereof other than by mail or on at least three days' notice if given by mail. Special meetings shall be called by the chairman or the President in like manner and on like notice on the written request of any two or more directors.

Section 3.09 Telephone Meetings. Board of Directors or Board of Directors committee meetings may be held by means of telephone conference or other communications equipment by means of which all persons participating in the meeting can hear each other and be heard. Participation by a director in a meeting pursuant to this Section shall constitute presence in person at such meeting.

Section 3.10 Adjourned Meetings. A majority of the directors present at any meeting of the Board of Directors, including an adjourned meeting, whether or not a quorum is present, may adjourn and reconvene such meeting to another time and place. At least 24 hours' notice of any adjourned meeting of the Board of Directors shall be given to each director whether or not present at the time of the adjournment, if such notice shall be given by one of the means specified in **Section 3.11** hereof other than by mail, or at least three days' notice if by mail. Any business may be transacted at an adjourned meeting that might have been transacted at the meeting as originally called.

Section 3.11 Notices. Subject to Section 3.08, Section 3.10 and Section 3.12 hereof, whenever notice is required to be given to any director by applicable law, the Certificate of Incorporation or these by-laws, such notice shall be deemed given effectively if given in person or by telephone, mail addressed to such director at such director's address as it appears on the records of the Corporation, facsimile, e-mail or by other means of electronic transmission.

Section 3.12 Waiver of Notice. Whenever notice to directors is required by applicable law, the Certificate of Incorporation or these by-laws, a waiver thereof, in writing signed by, or by electronic transmission by, the director entitled to the notice, whether before or after such notice is required, shall be deemed equivalent to notice. Attendance by a director at a meeting shall constitute a waiver of notice of such meeting except when the director attends a meeting for the express purpose of objecting, at the beginning of the meeting, to the transaction of any business on the ground that the meeting was not lawfully called or convened. Neither the business to be transacted at, nor the purpose of, any regular or special Board of Directors or committee meeting need be specified in any waiver of notice.

Section 3.13 Organization. At each meeting of the Board of Directors, the chairman or, in his or her absence, another director selected by the Board of Directors shall preside. The secretary shall act as secretary at each meeting of the Board of Directors. If the secretary is absent from any meeting of the Board of Directors, an assistant secretary shall perform the duties of secretary at such meeting; and in the absence from any such meeting of the secretary and all assistant secretaries, the person presiding at the meeting may appoint any person to act as secretary of the meeting.

Section 3.14 Quorum of Directors. The presence of a majority of the Board of Directors shall be necessary and sufficient to constitute a quorum for the transaction of business at any meeting of the Board of Directors.

Section 3.15 Action by Majority Vote. Except as otherwise expressly required by these by-laws, the Certificate of Incorporation or by applicable law, the vote of a majority of the directors shall be the act of the Board of Directors.

Section 3.16 Action Without Meeting. Unless otherwise restricted by the Certificate of Incorporation or these by-laws, any action required or permitted to be taken at any meeting of the Board of Directors or of any committee thereof may be taken without a meeting if all directors or members of such committee, as the case may be, consent thereto in writing or by electronic transmission, and the writings or electronic transmissions are filed with the minutes of proceedings of the Board of Directors or committee in accordance with applicable law.

Section 3.17 Committees of the Board of Directors. The Board of Directors may designate one or more committees, each committee to consist of one or more of the directors of the Corporation. The Board of Directors may designate one or more directors as alternate members of any committee, who may replace any absent or disqualified member at any meeting of the committee. If a member of a committee shall be absent from any meeting, or disqualified from voting thereat, the remaining member or members present at the meeting and not disqualified from voting, whether or not such member or members constitute a quorum, may unanimously appoint another member of the Board of Directors to act at the meeting in the place of any such absent or disqualified member. Any such committee, to the extent permitted by applicable law, shall have and may exercise all the powers and authority of the Board of Directors in the management of the business and affairs of the Corporation and may authorize the seal of the Corporation to be affixed to all papers that may require it to the extent so authorized by the Board of Directors. Unless the Board of Directors provides otherwise, at all meetings of such committee, a majority of the then authorized members of the committee shall constitute a quorum for the transaction of business, and the vote of a majority of the members of the committee present at any meeting at which there is a quorum shall be the act of the committee. Each committee shall keep regular minutes of its meetings. Unless the Board of Directors provides otherwise, each committee designated by the Board of Directors may make, alter and repeal rules and procedures for the conduct of its business. In the absence of such rules and procedures each committee shall conduct its business in the same manner as the Board of Directors conducts its business pursuant to this Article III.

ARTICLE IV OFFICERS

Section 4.01 Positions and Election. The officers of the Corporation shall be elected annually by the Board of Directors and shall include a president, a treasurer and a secretary. The Board of Directors, in its discretion, may also elect a chairman (who must be a director), one or more vice chairmen (who must be directors) and one or more vice presidents, assistant treasurers, assistant secretaries and other officers. Any two or more offices may be held by the same person.

Section 4.02 Term. Each officer of the Corporation shall hold office until such officer's successor is elected and qualified or until such officer's earlier death, resignation or removal. Any officer elected or appointed by the Board of Directors may be removed by the Board of Directors at any time with or without cause by the majority vote of the members of the Board of Directors then in office. The removal of an officer shall be without prejudice to his or her contract rights, if any. The election or appointment of an officer shall not of itself create contract rights. Any officer of the Corporation may resign at any time by giving written notice of his or her resignation to the president or the secretary. Any such resignation shall take effect at the time specified therein or, if the time when it shall become effective shall not be specified therein, immediately upon its receipt. Unless otherwise specified therein, the acceptance of such resignation shall not be necessary to make it effective. Should any vacancy occur among the officers, the position shall be filled for the unexpired portion of the term by appointment made by the Board of Directors.

Section 4.03 The President. The president shall have general supervision over the business of the Corporation and other duties incident to the office of president, and any other duties as may be from time to time assigned to the president by the Board of Directors and subject to the control of the Board of Directors in each case.

Section 4.04 Vice Presidents. Each vice president shall have such powers and perform such duties as may be assigned to him or her from time to time by the chairman of the Board of Directors or the president.

Section 4.05 The Secretary. The secretary shall attend all sessions of the Board of Directors and all meetings of the stockholders and record all votes and the minutes of all proceedings in a book to be kept for that purpose, and shall perform like duties for committees when required. He or she shall give, or cause to be given, notice of all meetings of the stockholders and meetings of the Board of Directors, and shall perform such other duties as may be prescribed by the Board of Directors or the president. The secretary shall keep in safe custody the seal of the Corporation and have authority to affix the seal to all documents requiring it and attest to the same.

Section 4.06 The Treasurer. The treasurer shall have the custody of the corporate funds and securities, except as otherwise provided by the Board of Directors, and shall keep full and accurate accounts of receipts and disbursements in books belonging to the Corporation and shall deposit all moneys and other valuable effects in the name and to the credit of the Corporation in such depositories as may be designated by the Board of Directors. The treasurer shall disburse the funds of the Corporation as may be ordered by the Board of Directors, taking proper vouchers for such disbursements, and shall render to the president and the directors, at the regular meetings of the Board of Directors, or whenever they may require it, an account of all his or her transactions as treasurer and of the financial condition of the Corporation.

Section 4.07 Duties of Officers May Be Delegated. In case any officer is absent, or for any other reason that the Board of Directors may deem sufficient, the president or the Board of Directors may delegate for the time being the powers or duties of such officer to any other officer or to any director.

ARTICLE V

STOCK CERTIFICATES AND THEIR TRANSFER

Section 5.01 Certificates Representing Shares. The shares of stock of the Corporation shall be represented by certificates; provided that the Board of Directors may provide by resolution or resolutions that some or all of any class or series shall be uncertificated shares that may be evidenced by a book-entry system maintained by the registrar of such stock. If shares are represented by certificates, such certificates shall be in the form, other than bearer form, approved by the Board of Directors. The certificates representing shares of stock of each class shall be signed by, or in the name of, the Corporation by the chairman, any vice chairman, the president or any vice president, and by the secretary, any assistant secretary, the treasurer or any assistant treasurer. Any or all such signatures may be facsimiles. Although any officer, transfer agent or registrar whose manual or facsimile signature is affixed to such a certificate ceases to be such officer, transfer agent or registrar before such certificate has been issued, it may nevertheless be issued by the Corporation with the same effect as if such officer, transfer agent or registrar were still such at the date of its issue.

Section 5.02 Lost, Stolen or Destroyed Certificates. The Board of Directors may direct a new certificate or uncertificated shares to be issued in place of any certificate theretofore issued by the Corporation alleged to have been lost, stolen or destroyed upon the making of an affidavit of that fact by the owner of the allegedly lost, stolen or destroyed certificate. When authorizing such issue of a new certificate or uncertificated shares, the Board of Directors may, in its discretion and as a condition precedent to the issuance thereof, require the owner of the lost, stolen or destroyed certificate, or the owner's legal representative to give the Corporation a bond sufficient to indemnify it against any claim that may be made against the Corporation with respect to the certificate alleged to have been lost, stolen or destroyed or the issuance of such new certificate or uncertificated shares.

ARTICLE VI GENERAL PROVISIONS

Section 6.01 Seal. The board of directors may adopt and use a corporate seal. The seal of the Corporation shall be in such form as shall be approved by the Board of Directors. The seal may be used by causing it or a facsimile thereof to be impressed or affixed or reproduced or otherwise, as may be prescribed by law or custom or by the Board of Directors. Failure to affix the corporate seal, if any, shall not affect the validity of any instrument.

Section 6.02 Fiscal Year. The fiscal year of the Corporation shall be the calendar year.

Section 6.03 Checks, Notes, Drafts, Etc. All checks, notes, drafts or other orders for the payment of money of the Corporation shall be signed, endorsed or accepted in the name of the Corporation by such officer, officers, person or persons as from time to time may be designated by the Board of Directors or by an officer or officers authorized by the Board of Directors to make such designation.

Section 6.04 Dividends. Subject to applicable law and the Certificate of Incorporation, dividends upon the shares of capital stock of the Corporation may be declared by the Board of Directors at any regular or special meeting of the Board of Directors or by consent in writing. Dividends may be paid in cash, in property or in shares of the Corporation's capital stock, unless otherwise provided by applicable law or the Certificate of Incorporation.

Section 6.05 Conflict with Applicable Law or Certificate of Incorporation. These by-laws are adopted subject to any applicable law and the Certificate of Incorporation. Whenever these by-laws may conflict with any applicable law or the Certificate of Incorporation, such conflict shall be resolved in favor of such law or the Certificate of Incorporation.

ARTICLE VII AMENDMENTS

These by-laws may be amended, altered, changed, adopted and repealed or new by-laws adopted at any meeting of the Board of Directors.

Effective May 10, 2022

CERTIFICATION

I, Chandler D. Robinson, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Monopar Therapeutics 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: May 12, 2022

/s/ Chandler D. Robinson

Chandler D. Robinson
Chief Executive Officer

CERTIFICATION

I, Kim R. Tsuchimoto, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Monopar Therapeutics 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: May 12, 2022

/s/ Kim R. Tsuchimoto

Kim R. Tsuchimoto
Chief Financial Officer

**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 Quarterly Report on Form 10-Q of Monopar Therapeutics Inc. (the Company) for the three months ended March 31, 2022, as filed with the Securities and Exchange Commission on the date hereof (the Report), we, Chandler D. Robinson, and Kim R. Tsuchimoto, hereby certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that:

- (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.

/s/ Chandler D. Robinson

Chandler D. Robinson
Chief Executive Officer

May 12, 2022

/s/ Kim R. Tsuchimoto

Kim R. Tsuchimoto
Chief Financial Officer

May 12, 2022

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Monopar Therapeutics 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 the Form 10-Q), irrespective of any general incorporation language contained in such filing.