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 September 30, 2022

☐ **Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

For the transition period from to

Commission File Number: 001-39070

MONOPAR THERAPEUTICS INC.

(Exact name of registrant as specified in its charter)

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

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

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

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

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

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

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

The number of shares outstanding with respect to each of the classes of our common stock, as of October 31, 2022, is set forth below:

Class	**Number of shares outstanding**
Common Stock, par value $0.001 per share	12,855,735

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, resulting in direct price controls driving lower prices, other governmental regulations affecting cost requirements and structures for selling therapeutic products, and recent governmental legislation affecting other industries which may indirectly increase our costs of obtaining goods and services;

- the uncertain impact of the COVID-19 pandemic on our ability to advance our clinical programs and raise additional financing;

- the cumulative impact of domestic and global inflation or the potential for an economic recession increasing our costs of obtaining goods and services;

- the uncertain impact of the Russia-Ukraine war 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 December 31, 2021 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 October 31, 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 (RITs) 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 be able to secure such financing or 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 approvals 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, qualified third parties to conduct our active pharmaceutical ingredient manufacturing, our drug product manufacturing, our 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 war and resulting sanctions against Russia and Russian entities and Russian reduction in gas shipments to the EU and other allies have increased fuel costs, reduced supplies of a critical industrial requirement 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, may delay the manufacture and delivery of our clinical materials, may increase costs of other goods and services 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.

- Market variables, such as inflation of product costs, labor rates and fuel, freight and energy costs, as well as geopolitical events could potentially cause the Company to suffer significant increases in its operating and administrative expenses.

- 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 and market 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 is highly uncertain in its scope and impact of its negative effects which 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)

	September 30, 2022	December 31, 2021*
Assets		
Current assets:		
Cash and cash equivalents	$ 14,316,461	$ 20,303,869
Other current assets	55,700	217,745
Total current assets	14,372,161	20,521,614
Operating lease right-of-use-asset	72,889	-
Total assets	$ 14,445,050	$ 20,521,614
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable, accrued expenses and other current liabilities	$ 1,914,302	$ 1,580,543
Total current liabilities	1,914,302	1,580,543
Non-current operating lease liability	20,850	-
Total liabilities	1,935,152	1,580,543
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Common stock, par value of $0.001 per share, 40,000,000 shares authorized, 12,855,735 and 12,598,125 shares issued and outstanding at September 30, 2022, and December 31, 2021, respectively	12,856	12,598
Additional paid-in capital	61,361,740	60,220,016
Accumulated other comprehensive income (loss)	42,985	(3,160)
Accumulated deficit	(48,907,683)	(41,288,383)
Total stockholders' equity	12,509,898	18,941,071
Total liabilities and stockholders' equity	$ 14,445,050	$ 20,521,614

* 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)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	**2021**	**2022**	**2021**
Operating Expenses:				
Research and development	$ 1,732,230	$ 1,827,322	$ 5,488,633	$ 4,510,531
General and administrative	675,115	631,698	2,139,246	1,935,599
Total operating expenses	2,407,345	2,459,020	7,627,879	6,446,130
Loss from operations	(2,407,345)	(2,459,020)	(7,627,879)	(6,446,130)
Other income:				
Interest income	7,698	577	8,579	23,499
Net loss	(2,399,647)	(2,458,443)	(7,619,300)	(6,422,631)
Other comprehensive income:				
Foreign currency translation gain	25,519	9	46,145	2,726
Comprehensive loss	$ (2,374,128)	$ (2,458,434)	$ (7,573,155)	$ (6,419,905)
Net loss per share:				
Basic and diluted	$ (0.19)	$ (0.20)	$ (0.60)	$ (0.52)
Weighted average shares outstanding:				
Basic and diluted	12,754,685	12,582,728	12,664,387	12,432,318

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

Monopar Therapeutics Inc.

Condensed Consolidated Statements of Stockholders' Equity
Three and Nine Months Ended September 30, 2022
(Unaudited)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
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	12,620,592	12,621	60,703,139	(3,744)	(43,745,105)	16,966,911
Issuance of common stock to non-employee directors pursuant to vested restricted stock units	11,436	11	(11)	—	—	—
Issuance of common stock to employees pursuant to vested restricted stock units, net of taxes	28,177	28	(29,683)	—	—	(29,655)
Issuance of common stock upon exercise of stock options	40,532	41	—	—	—	41
Stock-based compensation (non-cash)	—	—	357,293	—	—	357,293
Offering costs	—	—	(35,846)	—	—	(35,846)
Net loss	—	—	—	—	(2,762,931)	(2,762,931)
Other comprehensive income	—	—	—	21,210	—	21,210
Balance at June 30, 2022	12,700,737	12,701	60,994,892	17,466	(46,508,036)	14,517,023
Issuance of common stock to non-employee directors pursuant to vested restricted stock units	11,436	11	(11)	—	—	—
Issuance of common stock to employees pursuant to vested restricted stock units, net of taxes	16,094	16	(10,688)	—	—	(10,672)
Issuance of common stock upon exercise of stock options	127,468	128	—	—	—	128
Stock-based compensation (non-cash)	—	—	390,741	—	—	390,741
Offering costs	—	—	(13,194)	—	—	(13,194)
Net loss	—	—	—	—	(2,399,647)	(2,399,647)
Other comprehensive income	—	—	—	25,519	—	25,519
Balance at September 30, 2022	12,855,735	$ 12,856	$ 61,361,740	$ 42,985	$ (48,907,683)	$ 12,509,898

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

Monopar Therapeutics Inc.

Condensed Consolidated Statements of Stockholders' Equity (continued)
Three and Nine Months Ended September 30, 2021
(Unaudited)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
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	12,569,933	12,570	59,161,975	(5,099)	(34,069,178)	25,100,268
Issuance of common stock to non-employee directors pursuant to vested restricted stock units	3,008	3	(3)	—	—	—
Issuance of common stock to employees pursuant to vested restricted stock units, net of taxes	9,787	10	(24,013)	—	—	(24,003)
Stock-based compensation (non-cash)	—	—	357,593	—	—	357,593
Net loss	—	—	—	—	(2,080,169)	(2,080,169)
Other comprehensive loss	—	—	—	(57)	—	(57)
Balance at June 30, 2021	12,582,728	12,583	59,495,552	(5,156)	(36,149,347)	23,353,632
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	4,880	5	(9,983)	—	—	(9,978)
Stock-based compensation (non-cash)	—	—	392,065	—	—	392,065
Net loss	—	—	—	—	(2,458,443)	(2,458,443)
Other comprehensive income	—	—	—	9	—	9
Balance at September 30, 2021	12,590,612	$ 12,591	$ 59,877,631	$ (5,147)	$ (38,607,790)	$ 21,277,285

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 Nine Months Ended September 30,	
	2022	**2021**
Cash flows from operating activities:		
Net loss	$ (7,619,300)	$ (6,422,631)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense (non-cash)	1,247,846	1,117,890
Changes in operating assets and liabilities, net		
Other current assets	162,017	(44,111)
Accounts payable, accrued expenses and other current liabilities	282,435	63,356
Operating lease right-of-use assets and liabilities, net	249	-
Net cash used in operating activities	(5,926,753)	(5,285,496)
Cash flows from financing activities:		
Cash proceeds from the sales of common stock under a Capital on Demand™ Sales Agreement with JonesTrading Institutional Services LLC, net of commissions, fees and offering costs of $338,153	-	10,925,312
Other offering costs	(49,040)	-
Taxes paid related to net share settlement of vested restricted stock units	(56,993)	(55,481)
Cash proceeds from the issuance of stock upon exercise of stock options	169	17,478
Net cash provided by (used in) financing activities	(105,864)	10,887,309
Effect of exchange rates	45,209	2,642
Net increase (decrease) in cash and cash equivalents	(5,987,408)	5,604,455
Cash and cash equivalents at beginning of period	20,303,869	16,737,109
Cash and cash equivalents at end of period	$ 14,316,461	$ 22,341,564
Supplemental non-cash flow information:		
Lease liability arising out of obtaining right-of-use asset	$ 92,359	-

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

MONOPAR THERAPEUTICS INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

September 30, 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 $48.9 million as of September 30, 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 November 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, treatment options and potential surges of new cases from current or future COVID-19 variants, 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 war and resulting sanctions against Russia and Russian entities or allies 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, may delay the manufacture of its clinical materials, may increase costs of other goods and services 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.

Market variables, such as inflation of product costs, labor rates and fuel, freight and energy costs, as well as geopolitical events could likely cause the Company to suffer significant increases in its operating and administrative expenses.

MONOPAR THERAPEUTICS INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

September 30, 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 interim unaudited condensed consolidated financial statements contain all normal, recurring adjustments necessary to present fairly the Company's condensed consolidated financial position as of September 30, 2022, and the Company's condensed consolidated results of operations and comprehensive loss for the three and nine months ended September 30, 2022, and 2021, and the Company's condensed consolidated cash flows for the nine months ended September 30, 2022, and 2021.

The interim 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

September 30, 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 October 2022, the Company analyzed its cash requirements at least through November 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 of90 days or less on the date of purchase to be cash equivalents. Cash equivalents as of September 30, 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 on the Company's condensed consolidated balance sheets includes any lease payments made and excludes lease incentives. The incremental borrowing taking into consideration 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 September 30, 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

September 30, 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 and nine months ended September 30, 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 September 30, 2022, and December 31, 2021.

Assets and Liabilities Measured at Fair Value on a Recurring Basis

September 30, 2022	**Level 1**	**Total**
Assets		
Cash equivalents[(1)]	$ 13,924,216	$ 13,924,216
Total	$ 13,924,216	$ 13,924,216

December 31, 2021	**Level 1**	**Total**
Assets		
Cash equivalents[(1)]	$ 20,014,205	$ 20,014,205
Total	$ 20,014,205	$ 20,014,205

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

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Net Loss per Share

Net loss per share for the three and nine months ended September 30, 2022, and 2021, is calculated by dividing net loss by the weighted-average shares of common stock outstanding during the periods. Diluted net loss per share for the three and nine months ended September 30, 2022, and 2021, is calculated by dividing net loss by the weighted-average shares of the sum of a) weighted average common stock outstanding (12,754,685 and 12,582,728 shares for the three months ended September 30, 2022, and 2021, respectively, and 12,664,387 and 12,432,318 shares for the nine months ended September 30, 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 September 30, 2022, and 2021, potentially dilutive securities included stock-based awards to purchase up to 1,928,152 and 1,761,007 shares of the Company's common stock, respectively. For the three and nine months ended September 30, 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 and nine months ended September 30, 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

September 30, 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 and nine months ended September 30, 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.

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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 September 30, 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 and nine months ended September 30, 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 September 30, 2022. The Company has filed its U.S. Federal and state tax returns for the year ended December 31, 2021, 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.

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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 issue40,000,000 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 nine months ended September 30, 2021, the Company sold1,104,047 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 nine months ended September 30, 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.

On April 20, 2022, the Company executed a new Capital on Demand^{TM} Sales Agreement with JonesTrading, 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. During the three and nine months ended September 30, 2022, the Company incurred $13,194 and $49,040, respectively, in expenses related to the execution of the Capital on Demand^{TM} Sales Agreement and in connection with the filing of the prospectus supplement. These expenses were recorded as offering costs on the Company's condensed consolidated statement of stockholders' equity for the period. During the three and nine months ended September 30, 2022, the Company did not sell any stock pursuant to this agreement.

As of September 30, 2022, the Company had 12,855,735 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 that 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. In April 2022, the Company's Board of Directors voted to increase the stock award pool to 5,100,000 (an increase of 2,000,000 shares of common stock), which was approved by the Company's stockholders in June 2022.

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During the three months ended September 30, 2022, the Company's Plan Administrator Committee granted to non-officer employees aggregate stock options for the purchase of 4,000 shares of the Company's common stock with exercise prices ranging from $1.83 to $2.35 per share which vest over 4 years All stock option grants have a 10-year term.

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 January 1, 2021	**1,258,577**	**$ 4.47**
Granted	403,476	6.27
Forfeited	(115,151)	6.49
Exercised	(2,913)	6.00
Balances at December 31, 2021	**1,543,989**	**4.78**
Granted[(1)]	582,064	2.80
Forfeited[(2)]	(337,103)	6.13
Exercised	(168,000)	0.001
Balances at September 30, 2022	**1,620,950**	**4.29**
Unvested options outstanding expected to vest[(3)]	510,286	**4.03**

(1) 582,064 options vest as follows: options to purchase 511,552 shares of the Company's common stock vest 6/48ths on the nine-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 $1.83 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.

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A summary of options outstanding as of September 30, 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	871,939	6.96	512,285	5.27
$5.01-$10.00	629,216	6.64	492,709	6.18
$10.01-$15.00	113,670	7.30	99,545	7.30
$15.01-$20.00	6,125	7.34	6,125	7.34
	1,620,950	**6.86**	**1,110,664**	**5.87**

Restricted stock unit activity under the Plan was as follows:

	Restricted Stock Units (#)	Weighted-Average Grant Date Fair Value per Unit ($)
Unvested balance at January 1, 2021	**40,066**	**12.93**
Granted	124,374	6.81
Vested	(49,758)	8.04
Forfeited	(3,220)	7.52
Unvested balance at January 1, 2022	**111,462**	**8.44**
Granted	403,522	2.80
Vested	(115,154)	4.27
Forfeited	(92,628)	4.01
Unvested Balance at September 30, 2022	**307,202**	**3.93**

During the three months ended September 30, 2022, and 2021, the Company recognized $204,360 and $140,501 of employee, non-employee director and consultant stock-based compensation expense as general and administrative expenses, respectively, and $186,381 and $251,564 as research and development expenses, respectively. During the nine months ended September 30, 2022, and 2021, the Company recognized $613,525 and $422,360 of employee, non-employee director and consultant stock-based compensation expense as general and administrative expenses, respectively, and $634,321 and $695,530 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 condensed consolidated statements of operations and comprehensive loss for stock-based compensation arrangements.

The fair value of options granted from inception to September 30, 2022, was based on the Black-Scholes option-pricing model assuming the following factors4.7 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.

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September 30, 2022

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Stock options granted	4,000	99,000	582,064	400,476
Weighted-average grant date fair value per share	$ 1.60	$ 3.96	$ 2.10	$ 4.48
Fair value of shares vested	$ 205,397	$ 280,883	$ 757,976	$ 838,901

At September 30, 2022, the aggregate intrinsic value of outstanding vested stock options was approximately $0.6 million (there was no unvested stock options that had intrinsic value) and the weighted-average exercise price in aggregate was $4.29 which includes $4.41 for fully vested stock options and $4.03 for stock options expected to vest. At September 30, 2022, unamortized unvested balance of stock-based compensation was $2.5 million, to be amortized over the following 2.6 years.

Note 5 - Related Party Transactions

As of September 30, 2022, Tactic Pharma, LLC ("Tactic Pharma"), the Company's initial investor, beneficially owned 33.3% of Monopar's common stock and during the three and nine months ended September 30, 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: Two of the Company's board members were also Managing Members of Tactic Pharma as of September 30, 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. 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.

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 September 30, 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 September 30, 2021, no expenses were incurred under the GEIS agreement. During the nine months ended September 30, 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 September 30, 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 24-month lease for 1,202 square feet of the office space for $2,379 per month. In May 2022, the Company entered into a 22-month lease for 939 square feet of additional office space for $1,859 per month.

As of September 30, 2022, in accordance with ASC 842,*Leases*, the two leases were recorded as an operating lease right-of-use ("ROU") asset and a lease liability included in accounts payable, accrued expenses and other current liabilities, and non-current operating lease liability on the Company's condensed consolidated balance sheets. The initial 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 condensed consolidated statements of operations and comprehensive loss. Amortization of the ROU asset commenced on April 1, 2022, and June 1, 2022, for the two operating leases, respectively. No ROU asset or lease liability was recorded in 2021 as the lease obligation was less than one year.

The components of lease expense were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Total lease costs	$ 14,057	$ 13,466	$ 37,134	$ 41,499

Maturities of the lease liability as of September 30, 2022 are as follows:

Fiscal Year	Operating Leases
December 31, 2022	$ 12,714
December 31, 2023	50,856
December 31, 2024	8,476
Total lease payments	72,046
Less: imputed interest	(3,395)
Total lease liability as of September 30, 2022	**$ 68,651**

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:

	As of September 30,	
	2022	2021
Lease term:		
Operating leases	1.42 years	-
Discount rate:		
Operating lease	6.50%	-

Supplemental balance sheet information:

	As of September 30,	
	2022	2021
ROU asset - non-current	$ 72,889	-
Total ROU asset	**$ 72,889**	**-**
Operating lease liability - current	$ 47,801	-
Operating lease liability - non-current	20,850	-
Total operating lease liabilities	**$ 68,651**	**-**

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.

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.

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.

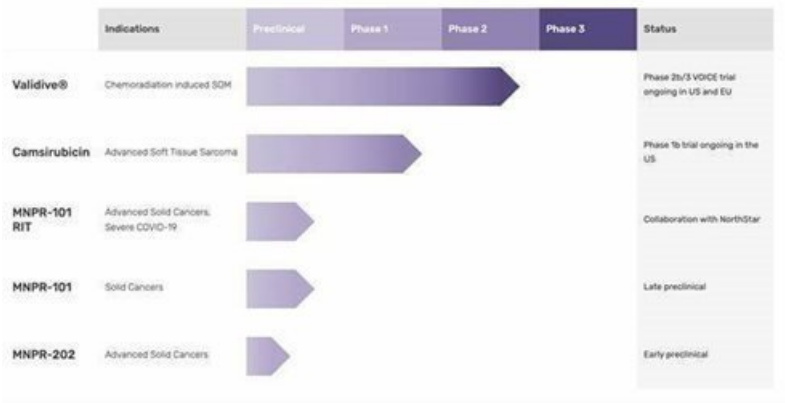
Financial Status

Our cash and cash equivalents as of September 30, 2022, was $14.3 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 November 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 November 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 were no further sales under our prior agreement.

On April 20, 2022, we entered into a new Capital on Demand™ 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, 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 HCI 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 ("SOM") 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. As of October 31, 2022, we have 73 clinical sites activated, enrolling patients in the U.S. and Europe. To be prepared for a positive go/no-go decision based on the interim analysis anticipated to occur in Q1 2023, 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 the 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 presently dosing patients at 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) and no drug-related cardiotoxicity has been observed to date up to the current dose-level. The open-label Phase 1b camsirubicin dose-escalation trial is continuing to enroll patients for additional cohorts until the maximum tolerable dose is reached. In October 2022, we announced that we will present an abstract and poster of the Phase 1b clinical trial data at the Connective Tissue Oncology Society Annual Meeting being held on November 16-19, 2022, in Vancouver, BC. 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 November 2023 and believe we have sufficient funds to advance the trial through that date. However, if camsirubicin reaches higher dose levels than we are anticipating, the Phase 1b clinical trial may still be dosing patients beyond November 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 **uP**AR-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 actively 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 has tested MNPR-202 in preclinical cancer models with promising results and is currently conducting additional preclinical studies with MNPR-202 with the aim to submit an abstract of the results to one or more scientific/medical conferences within the coming months. In October 2022, we announced that in collaboration with Dr. Anand Jeyasekharan of CSI Singapore, we will present an abstract and poster of the preclinical data of MNPR-202 at the American Society of Hematology 64th Annual Meeting being held on December 10-13, 2022, in New Orleans, LA.

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 recently successfully completed a Phase 3 clinical trial, 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 to the FDA and European Medicines Agency ("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 hopefully 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, help 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 marketing 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-pyrrilino 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, potentially addressing camsirubicin- and doxorubicin-resistant cancers.

- **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 Therapeutics), 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 September 30, 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 fees 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 compensation grants, including stock option and restricted stock unit ("RSU") grants. 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 holding 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 and nine months ended September 30, 2022, and 2021, was estimated using the simplified method. Forfeitures only include actual 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 and Nine Months Ended September 30, 2022, and 2021

The following table summarizes the results of our operations for the three and nine months ended September 30, 2022, and 2021:

	Three Months Ended September 30, (Unaudited)			Nine Months Ended September 30, (Unaudited)		
(in thousands)	**2022**	**2021**	**Variance**	**2022**	**2021**	**Variance**
Research and development expenses	$ 1,732	$ 1,827	$ (95)	$ 5,489	$ 4,511	$ 978
General and administrative expenses	675	632	43	2,139	1,935	204
Total operating expenses	2,407	2,459	(52)	7,628	6,446	1,182
Operating loss	(2,407)	(2,459)	52	(7,628)	(6,446)	(1,182)
Interest income	7	1	6	9	23	(14)
Net loss	$ (2,400)	$ (2,458)	$ 58	$ (7,619)	$ (6,423)	$ (1,196)

Research and Development ("R&D") Expenses

R&D expenses for the three months ended September 30, 2022 were $1,732,000, compared to $1,827,000 for the three months ended September 30, 2021. This represents a decrease of $95,000 attributed to (1) a decrease of $272,000 in R&D personnel costs and (2) a $60,000 net decrease of other R&D expenses, partially offset by an increase of $237,000 in Validive clinical trial-related and clinical material manufacturing-related expenses.

R&D expenses for the nine months ended September 30, 2022 were $5,489,000, compared to $4,511,000 for the nine months ended September 30, 2021. This represents an increase of $978,000 attributed to (1) an increase of $783,000 in Validive clinical trial-related and clinical material manufacturing-related expenses, (2) an increase of $400,000 in camsirubicin clinical trial expenses including patient dosing and manufacturing-related expenses (3) an increase of $86,000 in R&D consulting expenses partially offset by (1) a decrease of $261,000 in R&D personnel costs and (2) a $30,000 net decrease of other R&D expenses.

General and Administrative Expenses

General and administrative ("G&A") expenses for the three months ended September 30, 2022 were $675,000, compared to $632,000 for the three months ended September 30, 2021. This represents an increase of $43,000 primarily attributed to an increase in G&A salaries and benefits.

G&A expenses for the nine months ended September 30, 2022 were $2,139,000, compared to $1,935,000 for the nine months ended September 30, 2021. This represents an increase of $204,000 primarily attributed to an increase in G&A salaries and benefits.

Interest Income

Interest income for the three months ended September 30, 2022, increased by $7,000 compared to the three months ended September 30, 2021, due to interest received on refundable R&D credits from the Internal Revenue Service.

Interest income for the nine months ended September 30, 2022, decreased by $14,000 compared to the nine months ended September 30, 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 $48.9 million as of September 30, 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 potential 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 October 31, 2022, will fund our planned operations at least through November 30, 2023.

We invest our cash in a money market account.

Cash Flows

The following table provides information regarding our cash flows for the nine months ended September 30, 2022, and 2021.

	Nine Months Ended September 30, (Unaudited)		
(in thousands)	**2022**	**2021**	**Variance**
Net cash used in operating activities	$ (5,927)	$ (5,285)	$ (642)
Net cash provided by (used in) financing activities	(106)	10,887	(10,993)
Effect of exchange rates	45	3	42
Net increase (decrease) in cash and cash equivalents	$ (5,988)	$ 5,605	$ (11,593)

Cash Flow Used in Operating Activities

The increase of $642,000 in cash flow used in operating activities during the nine months ended September 30, 2022, compared to the nine months ended September 30, 2021, was primarily a result of increases in R&D cash operating expenses.

Cash Flow Used in Investing Activities

There was no cash flow used in investing activities for the nine months ended September 30, 2022, and 2021.

Cash Flow Provided by (Used in) Financing Activities

The decrease in cash flow provided by financing activities during the nine months ended September 30, 2022, compared to the nine months ended September 30, 2021, of $10,993,000 was primarily due to the proceeds from sales of our common stock under an at-the-market sales program during the nine months ended September 30, 2021. We did not have any sales of our common stock during the nine months ended September 30, 2022.

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 clinical development and regulatory requirements 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 October 31, 2022, will fund our obligations at least through November 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;
- the scope, progress, timing, cost and results of research, preclinical development and clinical trials and regulatory requirements for 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 management, operational, record keeping, and other 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 license , milestone or royalty payments under these arrangements.

Expenditures are expected to increase in the fourth 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
- increased employee compensation and consultant fees to support the increased scope of activities required for the progress of 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 fourth 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 share or 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 HCI 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 October 31, 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 Phase 1b dose escalation 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 September 30,2021 no expenses were incurred under the GEIS agreement. During the nine months ended September 30, 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. 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 October 31, 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.

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 September 30, 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 September 30, 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 Demand TM 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 Demand™ 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. To date we have not sold any shares under the agreement

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

The amount of proceeds from the Capital on Demand™ 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 6. Exhibits

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

Exhibit	Document	Incorporated by Reference From:
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: November 10, 2022

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

MONOPAR THERAPEUTICS INC.

Dated: November 10, 2022

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

EXHIBIT 31.1

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: November 10, 2022

/s/ Chandler D. Robinson
Chandler D. Robinson
Chief Executive Officer

EXHIBIT 31.2

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: November 10, 2022

/s/ Kim R. Tsuchimoto
Kim R. Tsuchimoto
Chief Financial Officer

EXHIBIT 32.1

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 and nine months ended September 30, 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

November 10, 2022

/s/ Kim R. Tsuchimoto
Kim R. Tsuchimoto
Chief Financial Officer

November 10, 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.