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, 2024

☐ **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, 2024, is set forth below:

Class	**Number of shares outstanding**
Common Stock, par value $0.001 per share	5,277,796

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 in order for us to support continued clinical, regulatory and commercial development of our programs and to make contractual upfront and future milestone payments, as well as our ability to further raise additional funds in the future to support any existing or future product candidate programs through completion of clinical trials, the approval processes and, if applicable, commercialization;
- our ability to raise funds on acceptable terms;
- 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 or any development partners' research and development activities, including preclinical studies, clinical trials, regulatory submissions, and manufacturing and quality expenses;
- known and unknown risks associated with developing radiopharmaceutical therapeutics and imaging agents and copper-chelating therapies;
- the uncertainty of timeframes for our clinical trials and regulatory reviews for approval to market products;
- our ability to address the fulfillment and logistical challenges posed by the potential time-limited shelf-life of our current radiopharmaceutical programs or future drug candidates;
- our ability to obtain an adequate supply at reasonable costs of radioisotopes that we are currently using or that we may incorporate into our drug candidates;
- uncertainties related to the regulatory discussions we intend to initiate related to ALXN-1840 and the outcome thereof;
- 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 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 of required additional financing at acceptable terms;
- the impact of the U.S. Presidential and Congressional election results affecting the economy and future 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 or imaging products, and recent governmental legislation affecting other industries which may indirectly increase our costs of obtaining goods and services and our cost of capital;
- the uncertain impact any resurgence of COVID-19 or another pandemic could have on our ability to advance our clinical programs and raise additional financing;
- the cumulative impact of domestic and global inflation, volatility in financial markets and/or the potential for an economic recession increasing our costs of obtaining goods and services or making financing more difficult to obtain on acceptable terms or at all;
- the uncertain impact of the Russia-Ukraine war, the Israel-Hamas war, or any potential future conflicts on our clinical material manufacturing expenses and timelines, as well as on general political, economic, trade and financial market conditions; and
- uncertainty of our financial projections and operational timelines and the development of new competitive products and technologies.

Although we believe that the risk assessments identified in such forward-looking statements are appropriate, we can give no assurance that such risks will materialize. Cautionary statements are disclosed in this Quarterly Report on Form 10-Q, including without limitation statements in the section entitled “Item 1A - Risk Factors,” addressing forward-looking statements. 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 projected in this information.

Summary Risk Factors

Our business is subject to numerous risks and uncertainties, including those highlighted in "Item 1A - Risk Factors" of our December 31, 2023 Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 28, 2024 and "Item 1A - Risk Factors" of this Quarterly Report on Form 10-Q. These risks include, among others, the following:

- We are a clinical stage biotechnology 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.

- Our ability to raise sufficient funds in order for us to support continued clinical, regulatory and commercial development of our programs and to make contractual upfront and future milestone payments, as well as our ability to further raise additional funds in the future to support any existing or future product candidate programs through completion of clinical trials, the approval processes and, if applicable, commercialization;

- Although a pivotal Phase 3 trial with ALXN-1840 has been completed, which met its primary endpoint as described elsewhere in this report, Alexion ended up terminating the ALXN-1840 program in Wilson disease based on review of results from Phase 2 mechanistic trials and discussions with regulatory authorities. In the near term, we will be focusing on assembling a regulatory package and initiating discussions with the U.S. Food and Drug Administration (FDA). There are uncertainties with respect to the outcome of these discussions and the additional capital needed for the program.

- The regulatory approval process can be lengthy, expensive and uncertain. The FDA and other regulatory agencies around the world could require us to perform additional nonclinical and/or clinical studies to obtain ALXN-1840 approval, which we may not be able to raise the capital to complete or the results of which may not meet the level of clinical or statistical significance required by the FDA and other regulatory agencies.

- 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 marketing and sale 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 could materially delay our program schedules and adversely affect our financial condition.

- If we or our licensees, development collaborators, or suppliers are unable to manufacture our products in sufficient quantities or at defined quality specifications, or are unable to obtain regulatory approvals for the manufacturing facility, we may be unable to develop and/or meet demand for our products as well as lose time to market and potential revenues.

- We rely on qualified third parties to conduct our active pharmaceutical ingredient manufacturing, our drug product manufacturing, non-clinical studies, and our clinical trials. If these third parties do not or cannot successfully carry out their contractual duties and meet expected deadlines or performance goals, the initiation or conduct of our clinical trials would be delayed and we may be unable to obtain regulatory approval for, or commercialize, our current product candidates or any future products, and our financial condition would be adversely affected.

- Radiopharmaceutical technology is a relatively novel approach to cancer imaging and treatment, which may create significant and potentially unpredictable challenges for it, including the availability of radioisotopes, potential misconception about the safety of radiopharmaceuticals, and low market uptake due to its novelty. Perceptions of these challenges may make it more difficult to raise funding as we focus efforts on our radiopharmaceutical programs.

- 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 access to critical supplies and may cause shipping delays. Separately, the Israel-Hamas war has created additional uncertainties. The broader political, economic, trade and financial market consequences are uncertain at this time, which may increase the cost of supplies for our clinical materials, delay the manufacture of our clinical materials, restrict the availability of radioisotopes, 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 and preclinical 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 likely cause us to suffer significant increases in our operating and administrative expenses.

- Unstable market and economic conditions, such as volatility in the markets due to concerns about bank stability and economic challenges due to inflation, may have serious adverse consequences on our ability to raise funds, which may cause us to delay, restructure or cease our operations.

- The impact of the U.S. Presidential and Congressional election results affecting the economy and future government laws and regulations including potential 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 or imaging products, and recent governmental legislation affecting other industries which may indirectly increase our costs of obtaining goods and services and our cost of capital;

- We face significant competition from other radiopharmaceutical, 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 in our industry have greater organizational capabilities, much higher available capital resources, and established marketing and sales resources and experience 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 develop and 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 operational and compensation costs, and our business would be materially disrupted.

- Any future or long-term impacts of COVID-19 or any other pandemic remain uncertain, and their scope and impact could have a substantial negative bearing 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, 2024	December 31, 2023*
Assets		
Current assets:		
Cash and cash equivalents	$ 6,020,084	$ 7,266,080
Other current assets	49,570	66,433
Total current assets	6,069,654	7,332,513
Operating lease right-of-use asset	—	12,646
Total assets	$ 6,069,654	$ 7,345,159
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable, accrued expenses and other current liabilities	$ 1,122,867	$ 1,757,393
Total liabilities	1,122,867	1,757,393
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Common stock, par value of $0.001 per share, 40,000,000 shares authorized, 3,525,079 and 2,980,900 shares issued and outstanding as of September 30, 2024, and December 31, 2023, respectively **	3,525	2,981
Additional paid-in capital	69,821,281	65,805,134
Accumulated other comprehensive loss	(10,991)	(14,132)
Accumulated deficit	(64,867,028)	(60,206,217)
Total stockholders' equity	4,946,787	5,587,766
Total liabilities and stockholders' equity	$ 6,069,654	$ 7,345,159

* Derived from the Company's audited consolidated financial statements.
** Information pertaining to number of shares outstanding gives retroactive effect to a 1 for 5 reverse stock split that became effective on August 12, 2024.

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,	
	2024	**2023**	**2024**	**2023**
Operating expenses:				
Research and development	$ 984,278	$ 1,316,520	$ 3,081,366	$ 4,564,602
General and administrative	590,624	749,474	2,005,711	2,354,645
Total operating expenses	1,574,902	2,065,994	5,087,077	6,919,247
Loss from operations	(1,574,902)	(2,065,994)	(5,087,077)	(6,919,247)
Other income	171,282	—	171,282	—
Interest income	99,344	112,260	254,984	330,966
Net loss	(1,304,276)	(1,953,734)	(4,660,811)	(6,588,281)
Other comprehensive income (loss):				
Foreign currency translation gain (loss)	5,176	6,930	5,924	(8,254)
Unrealized gain (loss) on investments	(24,425)	(10,203)	(2,783)	3,261
Comprehensive loss	$ (1,323,525)	$ (1,957,007)	$ (4,657,670)	$ (6,593,274)
Net loss per share:				
Basic and diluted	$ (0.37)	$ (0.69)	$ (1.36)	$ (2.43)
Weighted average shares outstanding:				
Basic and diluted**	3,520,398	2,823,680	3,419,321	2,710,356

** Information pertaining to number of shares outstanding and per share data gives retroactive effect to a 1 for 5 reverse stock split that became effective on August 12, 2024.

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, 2024
(Unaudited)

	Common Stock**		Additional Paid-in Capital**	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at January 1, 2024	2,980,900	$ 2,981	$ 65,805,134	$ (14,132)	$ (60,206,217)	$ 5,587,766
Issuance of common stock under a Capital on Demand™ Sales Agreement with JonesTrading Institutional Services, LLC, net of commissions, fees and offering costs of $81,932	509,061	509	3,193,801	—	—	3,194,310
Issuance of common stock to employees pursuant to vested restricted stock units, net of taxes	6,875	6	(10,745)	—	—	(10,739)
Stock-based compensation (non-cash)	—	—	328,661	—	—	328,661
Net loss	—	—	—	—	(1,641,226)	(1,641,226)
Other comprehensive income, net	—	—	—	18,363	—	18,363
Balance at March 31, 2024	3,496,836	3,496	69,316,851	4,231	(61,847,443)	7,477,135
Issuance of common stock to employees pursuant to vested restricted stock units, net of taxes	6,731	7	(10,009)	—	—	(10,002)
Exercise of stock options	16,800	17	67	—	—	84
Stock-based compensation (non-cash)	—	—	334,390	—	—	334,390
Net loss	—	—	—	—	(1,715,309)	(1,715,309)
Other comprehensive income, net	—	—	—	4,027	—	4,027
Balance at June 30, 2024	3,520,367	3,520	69,641,299	8,258	(63,562,752)	6,090,325
Issuance of common stock to employees pursuant to vested restricted stock units, net of taxes	4,652	5	(16,538)	—	—	(16,533)
Stock-based compensation (non-cash)	—	—	199,122	—	—	199,122
Impact of reverse stock split fractional share round up	60	—	—	—	—	—
Offering costs related to at-the-market offering	—	—	(2,602)	—	—	(2,602)
Net loss	—	—	—	—	(1,304,276)	(1,304,276)
Other comprehensive loss, net	—	—	—	(19,249)	—	(19,249)
Balance at September 30, 2024	3,525,079	$ 3,525	$ 69,821,281	$ (10,991)	$ (64,867,028)	$ 4,946,787

** Information pertaining to number of shares outstanding gives retroactive effect to a 1 for 5 reverse stock split that became effective on August 12, 2024.

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, 2023
(Unaudited)

	Common Stock**		Additional Paid-in Capital**	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at January 1, 2023	2,589,310	$ 2,589	$ 61,882,142	$ 8,942	$ (51,804,021)	$ 10,089,652
Issuance of common stock under a Capital on Demand™ Sales Agreement with JonesTrading Institutional Services, LLC, net of commissions, fees and offering costs of $37,661	48,879	49	807,289	—	—	807,338
Issuance of common stock to non-employee directors pursuant to vested restricted stock units	2,027	2	(2)	—	—	—
Issuance of common stock to employees pursuant to vested restricted stock units, net of taxes	4,192	4	(16,831)	—	—	(16,827)
Stock-based compensation (non-cash)	—	—	476,209	—	—	476,209
Net loss	—	—	—	—	(2,434,556)	(2,434,556)
Other comprehensive income	—	—	—	22,845	—	22,845
Balance at March 31, 2023	2,644,408	2,644	63,148,807	31,787	(54,238,577)	8,944,661
Issuance of common stock under a Capital on Demand™ Sales Agreement with JonesTrading Institutional Services, LLC, net of commissions, fees and offering costs of $26,522	124,246	124	659,871	—	—	659,995
Issuance of common stock to non-employee directors pursuant to vested restricted stock units	2,028	2	(2)			—
Issuance of common stock to employees pursuant to vested restricted stock units, net of taxes	8,933	9	(16,622)	—	—	(16,613)
Stock-based compensation (non-cash)	—	—	473,296	—	—	473,296
Net loss	—	—	—	—	(2,199,991)	(2,199,991)
Other comprehensive loss	—	—	—	(24,565)	—	(24,565)
Balance at June 30, 2023	2,779,615	2,779	64,265,350	7,222	(56,438,568)	7,836,783
Issuance of common stock to non-employee directors pursuant to vested restricted stock units	51,972	52	265,571	—	—	265,623
Issuance of common stock to employees pursuant to vested restricted stock units, net of taxes	2,027	2	(2)	—	—	—
Issuance of common stock upon exercise of stock options	6,073	6	(8,213)	—	—	(8,207)
Stock-based compensation (non-cash)	—	—	474,138	—	—	474,138
Net loss	—	—	—	—	(1,953,734)	(1,953,734)
Other comprehensive loss	—	—	—	(3,273)	—	(3,273)
Balance at September 30, 2023	2,839,687	$ 2,839	$ 64,996,844	$ 3,949	$ (58,392,302)	$ 6,611,330

** Information pertaining to number of shares outstanding gives retroactive effect to a 1 for 5 reverse stock split that became effective on August 12, 2024.

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,	
	2024	**2023**
Cash flows from operating activities:		
Net loss	$ (4,660,811)	$ (6,588,281)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense (non-cash)	862,173	1,423,643
Changes in operating assets and liabilities, net		
Other current assets	16,976	(27,219)
Accounts payable, accrued expenses and other current liabilities	(628,297)	(1,120,537)
Operating lease right-of-use assets and liabilities, net	4,238	—
Net cash used in operating activities	(4,405,721)	(6,312,394)
Cash flows from investing activities:		
Purchase of short-term investments	(985,730)	(7,891,330)
Maturities of short-term investments	985,730	9,848,643
Net cash provided by investing activities	—	1,957,313
Cash flows from financing activities:		
Cash proceeds from the sales of common stock under a Capital on Demand™ Sales Agreement	3,192,618	1,734,326
Exercise of stock options	84	—
Taxes paid related to net share settlement of vested restricted stock units	(37,274)	(41,647)
Net cash provided by financing activities	3,155,428	1,692,679
Effect of exchange rates	4,297	(8,439)
Net decrease in cash and cash equivalents	(1,245,996)	(2,670,841)
Cash and cash equivalents at beginning of period	7,266,080	8,186,194
Cash and cash equivalents at end of period	$ 6,020,084	$ 5,515,353

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

MONOPAR THERAPEUTICS INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

September 30, 2024

Note 1 – Nature of Business and Liquidity

Nature of Business

Monopar Therapeutics Inc. ("Monopar" or the "Company") is a clinical-stage biotechnology company with late-stage ALXN-1840 for Wilson disease, and radiopharma programs including Phase 1-stage MNPR-101-Zr for imaging advanced cancers, and Phase 1a-stage MNPR-101-Lu and late preclinical-stage MNPR-101-Ac225 for the treatment of advanced cancers.

Liquidity

The Company has incurred an accumulated deficit of approximately $64.9 million as of September 30, 2024. 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 at-the-market sales agreements, private placements of convertible preferred stock and of common stock and cash provided in the camsirubicin asset purchase transaction. In October 2024, the Company raised approximately $18.7 million in total net proceeds from two financing events as disclosed under subsequent event section of this Form 10-Q. Management estimates that currently available cash will provide sufficient funds to enable the Company to meet its obligations at least into the first half of 2026. The Company's ability to fund its future operations, including the development of ALXN-1840, an investigational drug candidate for Wilson disease, and the continued clinical development of its radiopharmaceutical programs, 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.

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 2024, the Company analyzed its cash requirements at least through December 31, 2025 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.

Risks and Uncertainties

Risks Related to the Company's Financial Condition and Capital Requirements

Many, if not most, biotechnology companies never become profitable and are acquired, merge, sell major product assets or go out of business before successfully developing any product that generates revenue from commercial sales that enables profitability. The Company has incurred losses since inception, and expects to continue to incur substantial operating losses over the next several years. These losses stem from the clinical development of the Company's current and future licensed and/or purchased product candidates and will continue for the foreseeable future. As a result, the Company anticipates that it will seek to raise additional capital within the next 12 months to fund our future operations. The Company's ability to raise sufficient funds in order to support continued clinical, regulatory and commercial development and to make contractual future milestone payments, as well as to further raise additional funds in the future to support any existing or future product candidate programs through completion of clinical trials, the approval processes and, if applicable, commercialization are uncertain.

The amount of future losses and when, if ever, the Company would become profitable is uncertain. The Company's ability to generate revenue and achieve profitability will depend on, among other things, successful completion of the development of its product candidates; obtaining necessary regulatory approvals from the FDA and international regulatory agencies; establishing manufacturing/quality, sales, and marketing and distribution arrangements with third parties; obtaining adequate reimbursement by third-party payers; and raising sufficient funds to finance its activities. If the Company is unsuccessful at some or all of these undertakings, its business, financial condition, and results of operations are expected to be materially and adversely affected.

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, 2024, and the Company's condensed consolidated results of operations and comprehensive loss for the three and nine months ended September 30, 2024 and 2023, and the Company's condensed consolidated cash flows for the nine months ended September 30, 2024 and 2023.

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 condensed consolidated results of operations or cash flows which may be reported for the remainder of 2024 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, 2023, included in the Company's Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission (the "SEC") on March 28, 2024.

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 income or losses not reported in the condensed consolidated statements of operations and comprehensive loss, such as foreign currency translations gains and losses and unrealized gains and losses on debt security investments that are 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.

Cash Equivalents

The Company considers all highly liquid investments purchased with a maturity of three months or less on the date of purchase to be cash equivalents. Cash equivalents as of September 30, 2024 and December 31, 2023, consisted of two money market accounts and U.S. Treasury Bills.

Investments

The Company considers all of its investments in debt securities (U.S. Government or Agencies), with maturities at the date of purchase from over three months to one year to be available-for-sale securities. These investments are recorded at fair value with the unrealized gains and losses reflected in accumulated other comprehensive income (loss) on the Company's condensed consolidated balance sheets. Realized gains and losses from the sale of investments, if any are determined, are recorded net in the condensed consolidated statements of operations and comprehensive loss. The investments selected by the Company have a low level of inherent credit risk given they are issued by the U.S. government and any changes in their fair value are primarily attributable to changes in interest rates and market liquidity. Investments as of September 30, 2024 consisted of U.S. Treasury Bills with maturities of less than three months.

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, 2024, 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.

Fair Value of Financial Instruments

For financial instruments consisting of cash and cash equivalents, investments, 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, 2024 and 2023. The following table presents the assets that are reported at fair value on the Company's condensed consolidated balance sheets on a recurring basis. No values were recorded in Level 2 or Level 3 as of September 30, 2024 and December 31, 2023. The Company has no liabilities reported at fair value on a recurring basis

Assets Measured at Fair Value on a Recurring Basis

September 30, 2024	**Level 1**	**Total**
Assets:		
Cash equivalents(1)	$ 5,795,869	$ 5,795,869
Total	$ 5,795,869	$ 5,795,869

December 31 2023	**Level 1**	**Total**
Assets:		
Cash equivalents(1)	$ 6,544,910	$ 6,544,910
Total	$ 6,544,910	$ 6,544,910

(1) Cash equivalents as of September 30, 2024 and December 31, 2023, represent the fair value of the Company’s investment in two money market accounts and U.S. Treasury Bills with maturities at the date of purchase of three months or less.

Net Loss per Share

Net loss per share for the three and nine months ended September 30, 2024 and 2023, 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, 2024 and 2023, is calculated by dividing net loss by the weighted-average shares of the sum of a) weighted average common stock outstanding (3,520,398 and 2,823,680 shares for the three months ended September 30, 2024 and 2023 respectively, 3,419,321 and 2,710,356 shares for the three and nine months ended September 30, 2024 and 2023 respectively) and b) potentially dilutive shares of common stock (such as stock options and restricted stock units) outstanding during the period determined using the treasury stock method. As of September 30, 2024 and 2023, potentially dilutive securities included stock-based awards to purchase up to 476,758 and 516,166 shares of the Company's common stock, respectively. For the three and nine months ended September 30, 2024 and 2023, 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 costs of 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 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.

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, 2024 and 2023, no milestones were met, and no royalties were earned; therefore, the Company did not pay or accrue/expense any license or royalty payments.

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, 2024 and 2023, 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.

See Note 8 for additional discussion regarding the Company's Licensing 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.

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, 2024 and December 31, 2023. 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, 2024 and 2023, 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 2023. The Company does not anticipate significant changes to its current uncertain tax positions through September 30, 2024.

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. For stock options granted in 2023, the expected volatility rates are estimated based on the Company's historical actual volatility over the three-year period from its initial public offering on December 18, 2019 through December 31, 2022. For awards granted during the three months ended September 30, 2024, the expected volatility rates were estimated based on the Company's historical actual volatility over the four-year period from its initial public offering on December 18, 2019, through December 31, 2023. 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.

Recent Accounting Pronouncements

In October 2023, the FASB issued Accounting Standards Update ("ASU") 2023-06, *Disclosure Improvements, Codification Amendments in Response to the SEC's Disclosure Update and Simplification Initiative*. The ASU incorporates certain U.S. Securities and Exchange Commission (SEC) disclosure requirements and are expected to clarify or improve disclosure and presentation requirements of a variety of Codification Topics, allow users to more easily compare entities subject to the SEC's existing disclosures with those entities that were not previously subject to the requirements, and align the requirements in the Codification with the SEC's regulations. The effective date for each amendment will be the date on which the SEC's removal of that related disclosure from Regulation S-X or Regulation S-K becomes effective with early adoption prohibited. For all other entities, the amendments will be effective two years later. In accordance with ASU 2023-06, the Company has added Note 7 – Net Loss per Share.

In November 2023, the FASB issued ASU No. *2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*. The ASU is intended to improve reportable segment disclosure requirements, primarily through enhanced disclosures about significant segment expenses. The purpose of the amendment is to enable investors to better understand an entity's overall performance and assess potential future cash flows. The guidance is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024, with early adoption permitted. The Company is currently evaluating the effect the amendments in ASU 2023-07 will have on its segment disclosures.

In December 2023, the FASB issued ASU No. 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*. The ASU improves income tax disclosure requirements and will require more detailed information on several income tax disclosures, such as income taxes paid and the income tax rate reconciliation table. The standard is effective for public business entities with annual periods beginning after December 15, 2024, and early adoption is permitted. The Company is currently evaluating the impact of this new standard on its condensed consolidated financial statements and related disclosures. The Company does not expect a material impact to its condensed consolidated financial statements based on adoption of this ASU.

Note 3 - Investments

As of September 30, 2024, the Company had two money market accounts and available-for-sale investments with contractual maturities of three months or less categorized as cash and cash equivalents as follows:

As of September 30, 2024	Cost Basis	Unrealized Gains	Aggregate Fair Value
U.S. Treasury Bills	$ 1,891,680	$ 6,454	$ 1,898,134
Money Market Accounts	3,897,735	—	3,897,735
Total	**$ 5,789,415**	**$ 6,454**	**$ 5,795,869**

As of September 30, 2024, there were no available-for-sale securities in an unrealized-loss position. There were no U.S. Treasury Bills classified as investments on the condensed consolidated balance sheet as of September 30, 2024.

As of December 31, 2023 the Company had two money market accounts and available-for-sale investments with contractual maturities of three months or less categorized as cash and cash equivalents as follows:

As of December 31, 2023	Cost Basis	Unrealized Gains	Aggregate Fair Value
U.S. Treasury Bills	$ 2,971,103	$ 9,237	$ 2,980,340
Money Market Accounts	3,564,570	—	3,564,570
Total	**$ 6,535,673**	**$ 9,237**	**$ 6,544,910**

As of December 31, 2023, there were no available-for-sale securities in an unrealized-loss position. There were no U.S. Treasury Bills classified as investments on the condensed consolidated balance sheet as of December 31, 2023.

See Note 2 for additional discussion regarding the Company's fair value measurements.

Note 4 - Capital Stock

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

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

Reverse Stock Split

On August 5, 2024, the Company conducted its Annual Meeting of Stockholders in which the stockholders approved among other items, a proposal to amend the Company's Second Amended and Restated Certificate of Incorporation to effect a reverse stock split of the outstanding shares, which provided the Board of Directors with authority to effect a reverse split within a specified range of ratios. Subsequently, the Board of Directors approved a reverse stock split of 1 for 5 shares of the Company's common stock in an attempt to regain compliance with the Nasdaq's continued listing requirements, which the reverse stock split did end up successfully accomplishing. The reverse stock split became effective at 5:00 pm on Monday August 12, 2024, and the Company's common stock commenced trading on a split-adjusted basis at the open of trading on Tuesday, August 13, 2024.

Furthermore, at the Annual Meeting of Stockholders, a proposal to amend the 2016 Stock Incentive Plan was approved. As a result, the total number of shares reserved for issuance under the Amended 2016 Plan would increase from 5,100,000 to 7,100,000 (pre-split). As a result of the above mentioned stock split, the total number of shares reserved for issuance was adjusted to 1,420,000.

The reverse stock split reduced the number of shares of the Company's common stock outstanding on August 12, 2024 from 17,601,827 to 3,520,427. Proportional adjustments were made to the Company's outstanding stock options, and restricted stock units. No fractional shares were issued in connection with the reverse stock split. Stockholders who would otherwise have held a fractional share of common stock were rounded up and issued one whole share.

The par value of the Company's common stock was unchanged at $0.001 per share. The number of authorized shares of common stock was also unchanged at 40,000,000 shares.

The reverse stock split did not modify the rights or preferences of the underlying common stock. The Company's stockholders' equity reflects the par value for all shares of common stock at $0.001 per share, with a corresponding increase in additional paid-in capital. All per-share amounts and numbers of shares in the accompanying financial statements and related notes have been retroactively adjusted to reflect the reverse stock split.

MONOPAR THERAPEUTICS INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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Sales of Common Stock

On April 20, 2022, the Company entered into a Capital on Demand™ Sales Agreement with JonesTrading Institutional Services LLC ("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 January 4, 2023, the Company filed a a prospectus related to the offer and sale of shares of common stock under this agreement of up to an aggregate amount of $6,505,642, under which $5,446,975 had been sold through September 30, 2024 and $1,058,667 was remaining on that date. Expenses related to these financing activities were recorded as offering costs (a reduction of additional paid in capital) on the Company's condensed consolidated statement of stockholders' equity for the period.

During the nine months ended September 30, 2024, the Company sold 509,061 shares of its common stock at an average gross price per share of $6.45 for net proceeds of $3,194,310, after fees and commissions of $81,932.

During the nine months ended September 30, 2023, the Company sold 173,124 shares of its common stock at an average gross price per share of $8.85 for net proceeds of $1,493,205, after fees and commissions of $38,312. In addition, the Company incurred legal, accounting and other fees totaling $25,872 for net proceeds after fees, commissions and expenses of $1,467,333.

Note 5 - 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 140,000 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 320,000 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 620,000 (an increase of 300,000 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 March 2022, the Company's Board of Directors voted to increase the stock award pool to 1,020,000 (an increase of 400,000 shares of common stock), which was approved by the Company's stockholders in June 2022. On August 5, 2024, the Company's Stockholders approved a proposal to amend the 2016 Stock Incentive Plan and a Reverse Stock Split. As a result of the proposal to amend the 2016 Stock Incentive Plan the total number of shares reserved for issuance under the Amended 2016 Plan would increase from 1,020,000 to 1,420,000. In August 2024 the Company's Board of Directors voted to approve the Reverse Stock Split at a ratio of 1-for-5.

During the nine months ended September 30, 2024, the Board of Directors granted to a consultant aggregate stock options for the purchase of 2,000 shares of the Company's common stock with an exercise price of $1.271 per share vesting monthly over 12 months and to officers aggregate stock options for the purchase of 30,001 shares of the Company's common stock with exercise prices ranging from $2.450 to $2.956 per share vesting over 4 years. In addition, during the nine months ended September 30, 2024, the Company's Plan Administrator Committee granted to non-officer employees and a new employee aggregate stock options for the purchase of 11,522 shares of the Company's common stock with exercise prices ranging from $1.899 to $2.751 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 December 31, 2023	**421,820**	**20.06**
Granted(1)	43,523	3.42
Forfeited(2)	(19,628)	15.88
Exercised	(16,800)	0.005
Balances at September 30, 2024	**428,915**	**19.35**
Unvested options outstanding expected to vest(3)	104,425	11.38

(1) 43,523 options vest as follows: options to purchase 2,000 shares of the Company's common stock vest monthly over one year; options to purchase 41,523 shares of the Company's common stock vest 6/48ths on the six-month anniversary of vesting commencement date and 1/48th per month thereafter.

(2) Forfeited options represent unvested shares and vested, unexercised and 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.

A summary of options outstanding as of September 30, 2024, 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
$0.00 - $25.00	282,170	6.71	182,266	5.61
$25.01 - $50.00	122,908	4.68	118,387	4.61
$50.01 - $75.00	22,612	5.23	22,612	5.23
$75.01 - $100.00	1,225	5.34	1,225	5.34
	428,915	**6.05**	**324,490**	**5.22**

Restricted stock unit activity under the Plan was as follows:

	Restricted Stock Units (#)	Weighted- Average Grant Date Fair Value per Unit ($)
Unvested balance at December 31, 2023	**83,617**	**17.01**
Granted(1)	5,997	3.26
Vested	(26,888)	19.43
Forfieted	(14,883)	15.84
Unvested Balance at September 30, 2024	**47,843**	**14.29**

(1) There were 5,997 restricted stock units granted during the nine months ended September 30, 2024. These units vest 6/48ths on the six-month anniversary of vesting commencement date and 3/48ths per quarter thereafter.

Stock option grants and fair values under the Plan were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Stock options granted	27,800	—	43,523	101,787
Weighted-average grant date fair value per share	$ 2.91	$ —	$ 2.72	$ 11.90
Fair value of shares vested	$ 145,763	$ 226,054	$ 505,504	$ 754,414

As of September 30, 2024, the aggregate intrinsic value of outstanding vested and unvested stock options was approximately $553,205 and $131,509 respectively. The weighted-average exercise price in aggregate was $19.35 which includes $21.92 for fully vested stock options and $11.38 for stock options expected to vest. As of September 30, 2024, unamortized unvested balance of stock-based compensation was $1.4 million, to be amortized over the following 2 years.

During the three months ended September 30, 2024 and 2023, the Company recognized $13,512 and $256,670 of employee, non-employee director and consultant stock-based compensation expense as general and administrative expenses, respectively, and $185,609 and $217,468 as research and development expenses, respectively. During the nine months ended September 30, 2024 and 2023, the Company recognized $325,589 and $757,303 of employee, non-employee director and consultant stock-based compensation expense as general and administrative expenses, respectively, and $536,584 and $666,340 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.

MONOPAR THERAPEUTICS INC.

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Note 6 - Related Party Transactions

As of September 30, 2024, Tactic Pharma, LLC ("Tactic Pharma"), the Company's initial investor, beneficially owned 24.3% of Monopar's common stock. During the three and nine months ended September 30, 2024, 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, 2024. 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 7 - Net Loss Per Share

Basic and diluted net loss per common share was calculated as follows:

(in thousands, except for net loss per share)	Three Months Ended September 30, 2024	2023	Nine Months Ended September 30, 2024	2023
Numerator:				
Net loss	$ (1,304)	$ (1,954)	$ (4,661)	$ (6,588)
Denominator:				
Weighted-average common shares outstanding, basic and diluted**	3,520	2,824	3,419	2,710
Net loss per common share, basic and diluted	$ (0.37)	$ (0.69)	$ (1.36)	$ (2.43)
Anti-dilutive potential common stock equivalents excluded from the calculation of net loss per share				
Stock options to purchase common stock**	429	423	429	423
Unvested restricted stock units**	48	106	48	106

** Information pertaining to number of shares outstanding gives retroactive effect to a 1 for 5 reverse stock split that became effective on August 12, 2024.

Note 8 – Commitments and Contingencies

License, Development and Collaboration Agreements

XOMA Ltd.

Pursuant to a non-exclusive license agreement with XOMA Ltd. for the humanization technology used in the development of MNPR-101, the Company is obligated to pay XOMA Ltd. clinical, regulatory and sales milestones which could reach up to $14.925 million if the Company achieves all milestones for MNPR-101. The agreement does not require the payment of sales royalties. There can be no assurance that the Company will achieve any milestones. As of September 30, 2024, the Company had not reached any milestones and has not been required to pay XOMA Ltd. any funds under this license agreement. The first milestone payment is payable upon first dosing of a human patient in a Phase 2 clinical trial. The Company's MNPR-101 radiopharma program is in Phase 1 and the Company cannot reliably predict when the program will enter Phase 2 if at all.

NorthStar Medical Radioisotopes, LLC ("NorthStar")

In June 2024, the Company entered into a long-term, non-exclusive master supply agreement for NorthStar to provide Monopar with the therapeutic radioisotope actinium-225 ("Ac-225"). The original collaboration agreement was amended at that time to clarify certain economic terms and those related to jointly developed intellectual property rights for Monopar's MNPR-101 for radiopharmaceutical use. Monopar has acquired those rights from NorthStar, together with certain broad, jointly developed intellectual property pertaining to MNPR-101, giving Monopar full ownership and title to its lead MNPR-101 radiopharmaceutical platform. Both companies will share ownership of the filed patent application on the use of PCTA as a linker with Ac-225, which has shown with MNPR-101 superior binding and yield with Ac-225 over the current industry-leading linker, DOTA.

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.

Note 9 – Subsequent Events

On October 23, 2024, the Company executed a License Agreement effective October 23, 2024 with Alexion Pharmaceuticals, Inc. ("Alexion, AstraZeneca Rare Disease" or "Alexion"), pursuant to which Alexion, AstraZeneca Rare Disease granted the Company an exclusive worldwide license for the development and commercialization of ALXN-1840, a drug candidate for Wilson disease that has progressed through a Phase 3 clinical trial that met its primary endpoint.

As initial upfront consideration for the License Agreement, the Company issued Alexion 387,329 shares of common stock (representing a 9.9% beneficial ownership interest in the Company upon issuance) and the Company has agreed to make an upfront cash payment of $4.0 million, which shall be payable in two installments, including a $1.0 million cash payment at the time of signing and a $3.0 million cash payment within ninety (90) days. The Company made the initial $1 million payment on October 24, 2024.

Additionally, pursuant to the license agreement, Alexion is eligible to receive milestones and royalties, as further described below.

The shares issued to Alexion were issued pursuant to a separate Common Stock Investment Agreement, also dated October 23, 2024, between the Company and Alexion (the "Equity Agreement"). Pursuant to the Equity Agreement, the Company agreed to anti-dilution provisions that entitle Alexion to additional shares of common stock so that the total number of shares issued thereunder continue to represent 9.9% of outstanding shares after any subsequent issuances of common stock through the next $25.0 million of common equity capital raised by the Company, subject to a maximum of 705,015 Shares (inclusive of the shares initially issued) unless the Company obtains stockholder approval. As of October 31, 2024, the Company has issued Alexion an additional 135,172 shares under these anti-dilution provisions (bringing the total number of shares issued to Alexion to 522,501) as a result of the financing transactions discussed below. The Equity Agreement also entitles Alexion to customary registration rights and the Company agreed to file a resale registration statement within forty-five (45) days of October 23, 2024.

As additional consideration, the Company will be obligated to pay Alexion aggregate milestone payments of up to $94.0 million, including regulatory approval and sales related milestone payments. Alexion is also entitled to receive tiered royalties based on net sales in the low to mid-double digit range. Alexion has a right of first negotiation regarding any rights that the Company intends to sublicense, and will receive a percentage in the mid-double digits of sublicensing income received by Company until the Licensed Product achieves sales. The Company also assumed a third party agreement from Alexion under which the Company will owe a third-party a single digit millions cash milestone payment upon regulatory approval in Europe and a single digit percentage royalty on net sales in Europe.

Subsequent to September 30, 2024, the Company sold 48,700 shares of its common stock at an average gross price per share of $21.22 for net proceeds of $1,007,934, after fees, commissions and expenses of $25,874 through an-at-the market offering,

On October 28, 2024, the Company entered into and executed a placement agent agreement with Rodman & Renshaw LLC in connection with registered public offering of 1,181,540 shares of the Company's common stock, par value $0.001 per share, at an offering price of $16.25 per Share. In connection with this offering, the Company entered into a securities purchase agreement with certain of the purchasers in the offering. The offering closed on October 30, 2024 and yielded net proceeds to the Company of approximately $17.7 million, after deducting placement agent fees and other estimated offering expenses.

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 biotechnology company with late-stage ALXN-1840 for Wilson disease, and radiopharma programs including Phase 1-stage MNPR-101-Zr for imaging advanced cancers, and Phase 1a-stage MNPR-101-Lu and late preclinical-stage MNPR-101-Ac225 for the treatment of advanced cancers.

Financial Status

Our cash, cash equivalents and investments as of September 30, 2024, were $6 million. Our primary funding source over the past three years was sales of shares of our common stock under at-the-market sales programs through Capital on Demand™ Sales Agreements with JonesTrading Institutional Services LLC ("Jones Trading"). As of October 31, 2024 we sold 557,761 shares of our common stock this year at an average gross price per share of $7.73 for net proceeds of $4,202,244 after fees and commissions of $107,806. On October 28, 2024, we entered into and executed a placement agent agreement with Rodman & Renshaw LLC in connection with a registered public offering of 1,181,540 shares of our common stock, par value $0.001 per share, at an offering price of $16.25 per Share. The offering closed on October 30, 2024 and yielded net proceeds from the offering of approximately $17.7 million, after deducting placement agent fees and other estimated offering expenses.

As discussed further below and elsewhere in this Quarterly Report, we expect that our current funds will be sufficient at least into the first half of 2026 for us to: (1) assemble a regulatory package and initiate discussions with the FDA for the in-licensed ALXN-1840 investigational drug candidate for Wilson disease; (2) continue to conduct and conclude our first-in-human imaging and dosimetry clinical trial with MNPR-101-Zr; (3) continue to conduct our first-in-human therapeutic clinical trial of MNPR-101-Lu; (4) advance our preclinical MNPR-101-Ac program into the clinic; and (5) invest in internal R&D projects to expand our radiopharma pipeline. We will require additional funding to further advance our clinical and preclinical programs and we anticipate that we will seek to raise additional capital within the next 12 months to fund our future operations.

Our Product Pipeline

ALXN-1840 for Wilson disease

Wilson disease is a rare and progressive genetic condition in which the body's pathway for removing excess copper is compromised. It affects one in 30,000 live births in the US. Over time this results in the build-up of toxic copper levels in the liver, brain, and other organs, leading to damage that greatly impacts a patient's life. Patients can develop a wide range of symptoms, including liver disease and/or psychiatric or neurological symptoms, such as personality changes, tremors and difficulty walking, swallowing or talking. In some cases, the damage and loss of function may be irreversible.

ALXN-1840 (bis-choline tetrathiomolybdate) is an investigational once-daily, oral medicine in development for the treatment of Wilson disease. This novel molecule is designed to selectively and tightly bind and remove copper from the body's tissues and blood. ALXN-1840 has been granted Orphan Drug Designation in the United States and orphan designation in the European Union for Wilson disease.

A pivotal Phase 3 trial with ALXN-1840 has been completed, which met its primary endpoint. The primary endpoint assessed copper mobilization over 48 weeks, defined as daily mean AUEC (Area Under the Effect Curve) for dNCC (directly measured non-ceruloplasmin-bound copper). In the trial, 214 patients were enrolled, and the trial was randomized, rater-blinded, and multi-centered, designed to evaluate the efficacy and safety of ALXN-1840 versus standard-of-care (SoC) in patients with Wilson disease aged 12 years and older. In the trial, people taking ALXN-1840 experienced rapid copper mobilization, with a response at four weeks and sustained through the 48 weeks. The primary endpoint demonstrated three-times greater copper mobilization from tissues compared to the SoC arm (Least Square Mean Difference [LSM Diff] 2.18 µmol/L; $p < 0.0001$), including in patients who had been treated previously for an average of 10 years.

Alexion ended up terminating the ALXN-1840 program in Wilson disease based on review of results from Phase 2 mechanistic trials and discussions with regulatory authorities. The Phase 2 mechanism of action studies failed to meet their primary objectives of demonstrating net-negative copper balance in Wilson disease patients during short-term treatment with ALXN-1840 and reducing hepatic copper concentration after treatment with ALXN-1840. The decision not to progress the ALXN-1840 program in Wilson disease was not related to any safety signals.

In the near term, we will be focusing on assembling a regulatory package and initiating discussions with the FDA. These activities will provide clarity on the additional capital needed for the program. As a result, the costs beyond the $4.0 million due at signing and within ninety (90) days pursuant to the license agreement, will largely be consultant time along with patent maintenance. These near-term expenses are estimated to be less than $1.0 million to assemble the detailed regulatory package and maintain the patent portfolio.

The regulatory approval process can be lengthy, expensive and uncertain. The FDA and other regulatory agencies around the world could require us to perform additional nonclinical and/or clinical studies to obtain ALXN-1840 approval, which we may not be able to raise the capital to complete or the results of which may not meet the level of clinical or statistical significance required by the FDA and other regulatory agencies. What the FDA and other regulatory agencies require for approval could have a material impact on the timelines and/or capital required to get ALXN-1840 approved. Even if approved, market adoption could be slower or lower than expected, especially given competition from existing therapies or new ones that get approved. We are planning to initially focus on Wilson disease patients with more severe symptoms, and this population could end up being smaller than we are anticipating. This population could be further reduced in size if the FDA or other regulatory agencies give us a more narrow label than anticipated. Being an orphan indication, this could result in a very small eligible patient population. Additionally, if the currently filed patents do not end up providing sufficient protection, we will be heavily reliant on the orphan drug designation protections in the US and EU.

MNPR-101 for Radiopharmaceutical Use, Development Update

The radiopharma space has had numerous positive recent developments and announcements, from acquisitions to clinical data to reimbursement rates to commercial demand. Since this past December alone, four significant acquisitions have been publicly announced or completed which have had upfront payments ranging from approximately $1 billion to over $4 billion (BMS/RayzeBio, AstraZeneca/Fusion Pharma, Eli Lilly/POINT BioPharma, and Novartis/Mariana Oncology).

Monopar has a proprietary first-in-class humanized monoclonal antibody, MNPR-101, that targets the urokinase plasminogen activator receptor ("uPAR"). uPAR is expressed on several of the more aggressive, deadly cancers including pancreatic, breast, ovarian, colorectal, and bladder cancers. Monopar has conjugated MNPR-101 to imaging and therapeutic radioisotopes for the purpose of creating highly precise radiopharmaceutical agents that have the potential to image and treat tumors expressing uPAR while reducing exposure to healthy tissues. In February 2024, we received regulatory clearance in Australia to commence a first-in-human Phase 1 imaging and dosimetry clinical trial with our novel radiopharmaceutical imaging agent MNPR-101-Zr (MNPR-101 conjugated to zirconium-89) in patients with advanced cancers, and in April, we launched the Phase 1 trial. In July 2024, we announced the enrollment of our first patient and in September 2024, we announced positive early clinical data validating the tumor-targeting ability of MNPR-101-Zr. In August 2024, we received regulatory clearance in Australia to commence a first-in-human Phase 1a clinical trial of our novel uPAR-targeted radiopharmaceutical therapy MNPR-101-Lu (MNPR-101 conjugated to lutetium-177) in patients with advanced solid cancers. We launched the trial in October 2024, and it is now active and open for patient enrollment.

In October, we presented clinical data at the European Association of Nuclear Medicine Annual Congress 2024 showing significant uptake of MNPR-101-Zr in a patient with advanced ovarian cancer together with preclinical and clinical data showing favorable biodistribution, tumor uptake, and low off-target binding of our uPAR-targeted radiopharmaceuticals MNPR-101-Zr, MNPR-101-Lu, and MNPR-101-Ac (MNPR-101 conjugated to actinium-225).

We are also actively exploring opportunities to expand our radiopharmaceutical pipeline primarily through internal development efforts. In October 2024, we announced the filing of a provisional patent application for new radiopharmaceutical compounds and a family of linkers used to connect radioisotopes with targeting agents, including our uPAR-targeting antibody MNPR-101.

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 subsequently had a positive 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 with the FDA and the 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 innovative treatments for patients with unmet medical needs. Key elements of our strategy to achieve this goal are to:

- **Assemble a regulatory package for ALXN-1840 and initiate discussions with the FDA.** We are planning to assemble a regulatory package to support a New Drug Application (NDA) approval for ALXN-1840 in Wilson disease patients with more severe symptoms.

- **Expand the development of MNPR-101 for radiopharmaceutical use as a therapeutic as well as a diagnostic imaging agent**. Based on promising preclinical data from our imaging and efficacy animal model studies in multiple cancers including triple-negative breast and pancreatic cancers and human clinical data from our MNPR-101-Zr Phase 1 trial validating the tumor-targeting ability of MNPR-101, we have prioritized significant resources and funds toward the development of our radiopharmaceutical programs. We have two open and active human clinical trials for our MNPR-101 radiopharmaceutical program; a Phase 1 imaging and dosimetry clinical trial of MNPR-101-Zr in patients with advanced cancers and a Phase 1a therapeutic clinical trial of MNPR-101-Lu also in patients with advanced cancers. In addition, we are continuing our preclinical development of MNPR-101-Ac, using the alpha-emitter actinium-225 conjugated to MNPR-101.

- **Expand our drug development pipeline through internal efforts, in-licensing and acquisition of product candidates.** We plan to continue the expansion of our drug development pipeline through internal research and development, acquiring or in-licensing additional product candidates, particularly those that leverage existing scientific and clinical data that helps reduce the risks of the next steps in clinical development. The focus on this front will include identifying both novel and established targets and candidates complementing our radiopharmaceutical and rare disease programs.

- **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 biotechnology 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, bis-choline tetrathiomolybdate, was ultimately acquired by Alexion in June 2018 for $764 million; Alexion was subsequently acquired by AstraZeneca). In October 2024, we in-licensed, ALXN-1840 from Alexion, AstraZeneca Rare Disease and plan to pursue regulatory approval and commercialization of this late-stage drug candidate for Wilson disease.

Revenues

We are an emerging growth company. We have no approved drugs and have not generated any revenues. To date, we have engaged in acquiring or in-licensing drug product candidates, and in entering into collaboration agreements for the preclinical testing and clinical development of our drug product candidates along with providing the infrastructure to support the clinical development of our drug product candidates. We do not anticipate revenues from operations until we complete testing and development of one of our drug product candidates and obtain marketing approval, or until 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, 2024, there were three recently issued accounting pronouncements that are described in more detail in Note 2 of our condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

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.

Going Concern Assessment

We apply 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 2024, we analyzed our cash requirements at least through December 31, 2025 and we have determined that, based upon our current available cash, we have no substantial doubt about our ability to continue as a going concern.

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 research and development 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. During the nine months ended September 30, 2024, we granted 2,000 options to purchase shares of our common stock to a consultant, 30,001 options to purchase shares of our common stock to officers and 11,522 options to purchase shares of our common stock to non-officer employees. For awards granted during the three and nine months ended September 30, 2024, the expected volatility rates are estimated based on our actual historical volatility over the four-year period from our initial public offering on December 18, 2019, through December 31, 2023. For awards granted during the three and nine months ended September 30, 2023, the expected volatility rates are estimated based on our actual historical volatility over the three-year period from our initial public offering on December 18, 2019, through December 31, 2022. The expected term for stock options granted during the three and nine months ended September 30, 2024, and 2023, was estimated using the simplified method. Forfeitures only include actual forfeitures to-date as we account 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, 2024 and 2023

The following table summarizes the results of our operations for the three and nine months ended September 30, 2024 and 2023:

	Three Months Ended September 30, (Unaudited)			Nine Months Ended September 30, (Unaudited)		
(in thousands)	**2024**	**2023**	**Variance**	**2024**	**2023**	**Variance**
Research and development expenses	$ 984	$ 1,317	$ (333)	$ 3,081	$ 4,564	$ (1,483)
General and administrative expenses	591	749	(158)	2,006	2,355	(349)
Total operating expenses	1,575	2,066	(491)	5,087	6,919	(1,832)
Operating loss	(1,575)	(2,066)	491	(5,087)	(6,919)	1,832
Other income	171	—	171	171	—	171
Interest income	99	112	(13)	255	331	(76)
Net loss	$ (1,305)	$ (1,954)	$ 649	$ (4,661)	$ (6,588)	$ 1,927

Research and Development ("R&D") Expenses

R&D expenses for the three months ended September 30, 2024 were $984,000, compared to $1,317,000 for the three months ended September 30, 2023. This represents a decrease of $333,000 attributed to (1) a decrease in camsirubicin manufacturing costs of $301,000 due to our decision to wind down that program, and (2) a decrease of $218,000 in Validive clinical trial-related expenses due to the closure of the trial in March 2023. These decreases were partially offset by a net increase of $186,000 due to other R&D expenses attributable to MNPR-101 for radiopharma use.

R&D expenses for the nine months ended September 30, 2024 were $3,081,000 compared to $4,564,000 for the nine months ended September 30, 2023. This represents a decrease of $1,483,000 attributed to (1) a decrease of $1,572,000 in Validive clinical trial-related expenses due to the closure of the trial in March 2023, and (2) a net decrease of $366,000 due to other R&D expenses. These decreases were partially offset by an increase of $455,000 in expenses for MNPR-101 for radiopharma use.

General and Administrative ("G&A") Expenses

G&A expenses for the three months ended September 30, 2024 were $591,000, compared to $749,000 for the three months ended September 30, 2023. This represents a decrease of $158,000 primarily attributed to (1) a reduction of stock based compensation expenses of $146,000 due to the full vesting of the 2020 grants in the fourth quarter of 2023, and (2) a decrease in stock-based compensation to the CEO and the board of directors of $64,000 as no equity awards have been issued to the CEO and the board of directors to date in 2024 partially offset by a net increase in consulting and other G&A expenses of $52,000.

G&A expenses for the nine months ended September 30, 2024 were $2,006,000, compared to $2,355,000 for the nine months ended September 30, 2023. This represents a decrease of $349,000 primarily attributed to (1) a reduction of stock based compensation expenses of $197,000 due to the full vesting of the 2020 grants in the fourth quarter of 2023, and (2) a decrease in stock-based compensation to the CEO and the board of directors of $197,000 as no equity awards were issued to the CEO and the board of directors to date in 2024 partially offset by a net increase in consulting, tax services and other G&A expenses of $45,000.

Other Income

Other income for the three and nine months ended September 30, 2024 increased by $171,000 versus the three and nine months ended September 30, 2023 due to the release of an accrued liability.

Interest Income

Interest income for the three months ended September 30, 2024, decreased by $13,000 versus the three months ended September 30, 2023. The reduction in the amount of interest received is a reflection of the lower daily average cash balance in the third quarter of 2024 versus the third quarter of 2023.

Interest income for the nine months ended September 30, 2024, decreased by $76,000 versus the nine months ended September 30, 2023, due to lower interest received due to a lower daily average cash balance in the nine months ended September 30, 2024 versus the nine months ended September 30, 2023.

Liquidity and Capital Resources

Sources of Liquidity

We have incurred losses and cumulative negative cash flows from operations since we commenced operations resulting in an accumulated deficit of approximately $64.9 million as of September 30, 2024. 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 variety of methods including and not limited to marketed offerings, rights offerings, debt financing, strategic partnerships or other sources of capital that may be available.

We anticipate that the currently available funds as of October 31, 2024 will fund our planned operations at least into the first half of 2026.

We invest our cash equivalents in two money market accounts and U.S. Treasury Bills and may consider expanding the instruments to include U.S Treasury Notes and U.S. Treasury bonds.

Cash Flows

The following table provides information regarding our cash flows for the nine months ended September 30, 2024 and 2023.

	Nine Months Ended September 30,		
		(Unaudited)	
(in thousands)	**2024**	**2023**	**Variance**
Net cash used in operating activities	$ (4,405)	$ (6,312)	$ 1,907
Net cash provided by investing activities	—	1,957	(1,957)
Net cash provided by financing activities	3,155	1,692	1,463
Effect of exchange rates	4	(8)	12
Net decrease in cash and cash equivalents	$ (1,246)	$ (2,671)	$ 1,425

During the nine months ended September 30, 2024 and 2023 we had a net cash outflow of $1,246,000 and $2,671,000, respectively. During the nine months ended September 30, 2024, versus the nine months ended September 30, 2023, the decrease in net cash outflow of $1,425,000 primarily consisted of a decrease in net cash provided by investing activities of $1,957,000 due to the purchases of investments versus certain investments maturities in 2023, partially offset by (1) a decrease in net cash used in operating activities of $1,907,000, (2) an increase in net cash provided by financing activities of $1,463,000 due to the increased sales of shares of our common stock under at-the-market sales programs and (3) an increase due to effect of foreign exchange rates.

Cash Flow Used in Operating Activities

The decrease of $1,907,000 in cash flow used in operating activities during the nine months ended September 30, 2024 compared to the nine months ended September 30, 2023 was primarily a result of lower net loss due to a reduction in research and development expenses.

Cash Flow Provided by Investing Activities

The cash provided by investing activities during the nine months ended September 30, 2024 and the cash provided by investing activities during the nine months ended September 30, 2023 represent our net investment in U.S. Treasury Bills maturing or invested in during the periods reported.

Cash Flow Provided by Financing Activities

The increase in cash flow provided by financing activities during the nine months ended September 30, 2024 compared to the nine months ended September 30, 2023 of $1,463,000 was primarily due to higher net proceeds from sales of our common stock under at-the-market sales programs during the nine months ended September 30, 2024 when compared to the sales of our common stock during the nine months ended September 30, 2023.

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. We will need substantial additional funding for clinical development prior to seeking regulatory approval. 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 or imaging 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:

- develop our ALXN-1840 investigational drug candidate as a treatment for Wilson disease;
- progress our MNPR-101-Zr imaging and dosimetry clinical trial in advanced cancer patients;
- progress our MNPR-101-Lu therapeutic clinical trial in advanced cancer patients;
- continue the preclinical activities and potentially advance MNPR-101-Ac into the clinic as a therapeutic in advanced cancer patients;
- support intellectual property initiatives for our Wilson disease and radiopharmaceutical programs;
- identify and potentially invent or license novel targets and drug candidates complementing our radiopharmaceutical programs, 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 in order to establish a reliable, high quality supply chain sufficient to support our clinical and specialized radiopharmaceutical 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, 2024 will fund our obligations at least into the first half of 2026. 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 development program for ALXN-1840 in Wilson disease;
- the clinical development progress of MNPR-101-Zr in imaging advanced cancers;
- the clinical development progress of MNPR-101-Lu as a therapeutic agent in advanced cancers;
- the progress of preclinical and clinical development of MNPR-101-Ac (the radioisotope actinium-225 conjugated to MNPR-101);
- the progress of preclinical activities towards identifying novel targets and candidates to complement our radiopharmaceutical programs;
- the number and characteristics of other drug product candidates that we may invent, license, acquire, 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, timing and outcomes of seeking, obtaining, and maintaining FDA and international regulatory approvals;
- 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.

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. Our spending could be significantly accelerated in the future 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 current funds, substantial additional long-term funding is needed to further develop our radiopharmaceutical and rare disease programs.

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, 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

Alexion, AstraZeneca Rare Disease

On October 23, 2024, we executed a License Agreement with Alexion Pharmaceuticals, Inc., pursuant to which Alexion granted us an exclusive worldwide license for the development and commercialization of ALXN-1840, a drug candidate for Wilson disease. As initial upfront consideration for the License Agreement, we issued Alexion 387,329 shares (representing 9.9% of our outstanding shares) of our common stock and agreed to make an upfront cash payment of $4.0 million. We agreed to an anti-dilution provision that entitles Alexion to receive additional shares at no cost to maintain their 9.9% ownership until we raise the next $25.0 million of common equity capital, subject to a maximum of 705,015 Shares unless we obtain stockholder approval. We have given customary registration rights to Alexion and agreed to file a resale registration statement within forty-five (45) days of October 23, 2024. To date, we have issued an aggregate of 522,501 shares of our common stock to Alexion.

A cash payment of $1.0 million was paid at the time of signing and the remaining $3.0 million is due to be paid within ninety (90) days. Additionally, we are obligated to milestone payments of up to $94.0 million for achievement of regulatory approval and sales related milestones. In addition, we are obligated to pay tiered royalties based on net sales in the low to mid-double digit range. We have also given Alexion the right of first negotiation regarding any rights should we intend to sublicense ALXN-1840. Furthermore, we will have to pay Alexion a percentage in the mid-double digits of any sublicensing income received by us. As part of this license agreement, we will also owe a third-party single digit millions cash milestone payment upon regulatory approval in Europe and a single digit percentage royalty on net sales in Europe.

NorthStar Medical Radioisotopes, LLC ("NorthStar")

In June 2024, we entered into a long-term, non-exclusive master supply agreement with NorthStar underwhich Northstar will provide us with the therapeutic radioisotope actinium-225 ("Ac-225"). The original collaboration agreement was amended at that time to clarify certain economic terms and those related to jointly developed intellectual property rights for our MNPR-101 for radiopharmaceutical use. We have acquired these rights from NorthStar, together with certain broad, jointly developed intellectual property pertaining to MNPR-101, giving us full ownership and title to our lead MNPR-101 radiopharmaceutical platform. We will jointly share ownership of the filed patent application on the use of PCTA as a linker with Ac-225, which has shown that MNPR-101 has superior binding and yield with Ac-225 over the current industry-leading linker, DOTA.

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, 2024, we had not reached any milestones and had not been required to pay XOMA Ltd. any funds under this license agreement. The first milestone payment is payable upon first dosing of a human patient in a Phase 2 clinical trial. We are currently conducting a Phase 1 clinical trial and cannot reliably predict when we will be able to commence a Phase 2 clinical trial, if at all.

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

We are currently leasing on a month-to-month basis office space for our 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, 2024, pursuant to Rules 13a-15(e) and 15d-15(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, 2024 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 28, 2024.

Our strategic focus on our radiopharmaceutical program could subject to us to concentrated risks.

As a result of our strategic decision to focus our efforts on our radiopharmaceutical program, a relatively novel approach to cancer imaging and treatment, and wind-down our camsirubicin and MNPR-202 programs, we face concentrated risks. Although the nature of the risks associated with our radiopharmaceutical program as described in Item 1A of our Annual Report on Form 10-K have not materially changed, the impacts from those risks should they be realized, or from perceptions of those risks in the market, could be more acute. In addition, our decision to wind-down our camsirubicin and MNPR-202 programs could adversely impact our stock price. Following our decision to wind-down our Validive program in 2023, our stock price suffered significant declines. We cannot predict what impact our decision to focus on our radiopharmaceutical program and wind-down our other programs will have on our stock price or financing prospects.

There are risks and uncertainties associated with our newly-acquired ALXN-1840 program.

Although a pivotal Phase 3 trial with ALXN-1840 has been completed, which met its primary endpoint as described elsewhere in this report, Alexion ended up terminating the ALXN-1840 program in Wilson disease based on review of results from Phase 2 mechanistic trials and discussions with regulatory authorities. The Phase 2 mechanism of action studies failed to meet their primary objectives of demonstrating net-negative copper balance in Wilson disease patients during short-term treatment with ALXN-1840 and reducing hepatic copper concentration after treatment with ALXN-1840. The decision not to progress the ALXN-1840 program in Wilson disease was not related to any safety signals.

In the near term, Monopar will be focusing on assembling a regulatory package and initiating discussions with the FDA. These activities will provide clarity on the additional capital needed for the program.

The regulatory approval process can be lengthy, expensive and uncertain. The FDA and other regulatory agencies around the world could require us to perform additional nonclinical and/or clinical studies to obtain ALXN-1840 approval, which we may not be able to raise the capital to complete or the results of which may not meet the level of clinical or statistical significance required by the FDA and other regulatory agencies. What the FDA and other regulatory agencies require for approval could have a material impact on the timelines and/or capital required to get ALXN-1840 approved. Even if approved, market adoption could be slower or lower than expected, especially given competition from existing therapies or new ones that get approved. We are planning to initially focus on Wilson disease patients with more severe symptoms, and this population could end up being smaller than we are anticipating. This population could be further be reduced in size if the FDA or other regulatory agencies give us a more narrow label than anticipated. Being an orphan indication, this could result in a very small eligible patient population. Additionally, if the currently filed patents do not end up providing sufficient protection, we will be heavily reliant on the orphan drug designation protections in the US and EU.

Item 5. Other Information

During the quarter ended September 30, 2024, no director or officer of the Company adopted or terminated a “Rule 10b5- 1 trading arrangement” or “non-Rule 10b5- 1 trading arrangement,” as each term is defined in Item 408(a) of Regulation S-K.

Item 6. Exhibits

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

Exhibit	Document	Incorporated by Reference From:
3.1	Second Amended and Restated Certificate of Incorporation	Form 10-K filed on March 26, 2018
3.2	Certificate of Amendment	Form 8-K filed on August 9, 2024
10.1*	License Agreement between Alexion and Monopar	Form 8-K filed on October 24, 2024
10.2	Common Stock Investment Agreement	Form 8-K filed on October 24, 2024
10.2	Placement Agency Agreement	Form 8-K filed on October 30, 2024
10.4	Form of Securities Purchase Agreement	Form 8-K filed on October 30, 2024
31.1	Certification of Chandler D. Robinson, Chief Executive Officer	Filed herewith
31.2	Certification of Karthik Radhakrishnan, Chief Financial Officer	Filed herewith
32.1	Certification of Chandler D. Robinson, Chief Executive Officer and Karthik Radhakrishnan, Chief Financial Officer	Filed herewith
101.INS	Inline XBRL Instance Document	
101.SCH	Inline XBRL Taxonomy Extension Schema	
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase	
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase	
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase	
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase	
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101)	

* Portions of this exhibit (indicated by asterisks) have been redacted in compliance with Regulation S-K Item 601(b)(10)(iv).

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 8, 2024

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

MONOPAR THERAPEUTICS INC.

Dated: November 8, 2024

By: /s/ Karthik Radhakrishnan
Name: Karthik Radhakrishnan
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 8, 2024

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

EXHIBIT 31.2

CERTIFICATION

I, Karthik Radhakrishnan, 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, 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 8, 2024

/s/ Karthik Radhakrishnan
Karthik Radhakrishnan
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 months ended September 30, 2024, as filed with the Securities and Exchange Commission on the date hereof (the Report), we, Chandler D. Robinson, and Karthik Radhakrishnan, 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 8, 2024

/s/ Karthik Radhakrishnan
Karthik Radhakrishnan
Chief Financial Officer

November 8, 2024

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.